RetCam 3

Ophthalmic Imaging System

User Manual

PN 21-100277 Rev. C
For use with
software version 5.1

CE

Caution: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

Clarity medical systems

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1 Introduction

The **RetCam3 Ophthalmic Imaging System** (system) is designed to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

Indications for Use

For general ophthalmic imaging, including retinal, corneal, and external.

Warnings and Cautions

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

WARNING: Prior to using the system, read all user safety information.

WARNING: Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.

WARNING: The RetCam system is designed and tested as a system. Omission or substitution of RetCam components may adversely affect system performance and is strongly not recommended.

WARNING: Unauthorized modifications or additions to the RetCam system (including hardware and software, etc.) could adversely affect system function and will void the warranty.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT use if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of exposure time necessary; no greater than 5 minutes.

WARNING: Use care when contacting the eye; i.e., use the least amount of pressure and/or movement necessary.

WARNING: A risk/benefit ratio must be assessed before confirming a patient for RetCam imaging if they are: photosensitive, concomitantly exposed to photosensitizing agents, or aphakic.

WARNING: To avoid the risk of electric shock, the equipment must be connected to a supply mains with protective earth**.**

WARNING: To mitigate the potential for excess light exposure, the user should avoid looking directly at the illuminated light source**.**

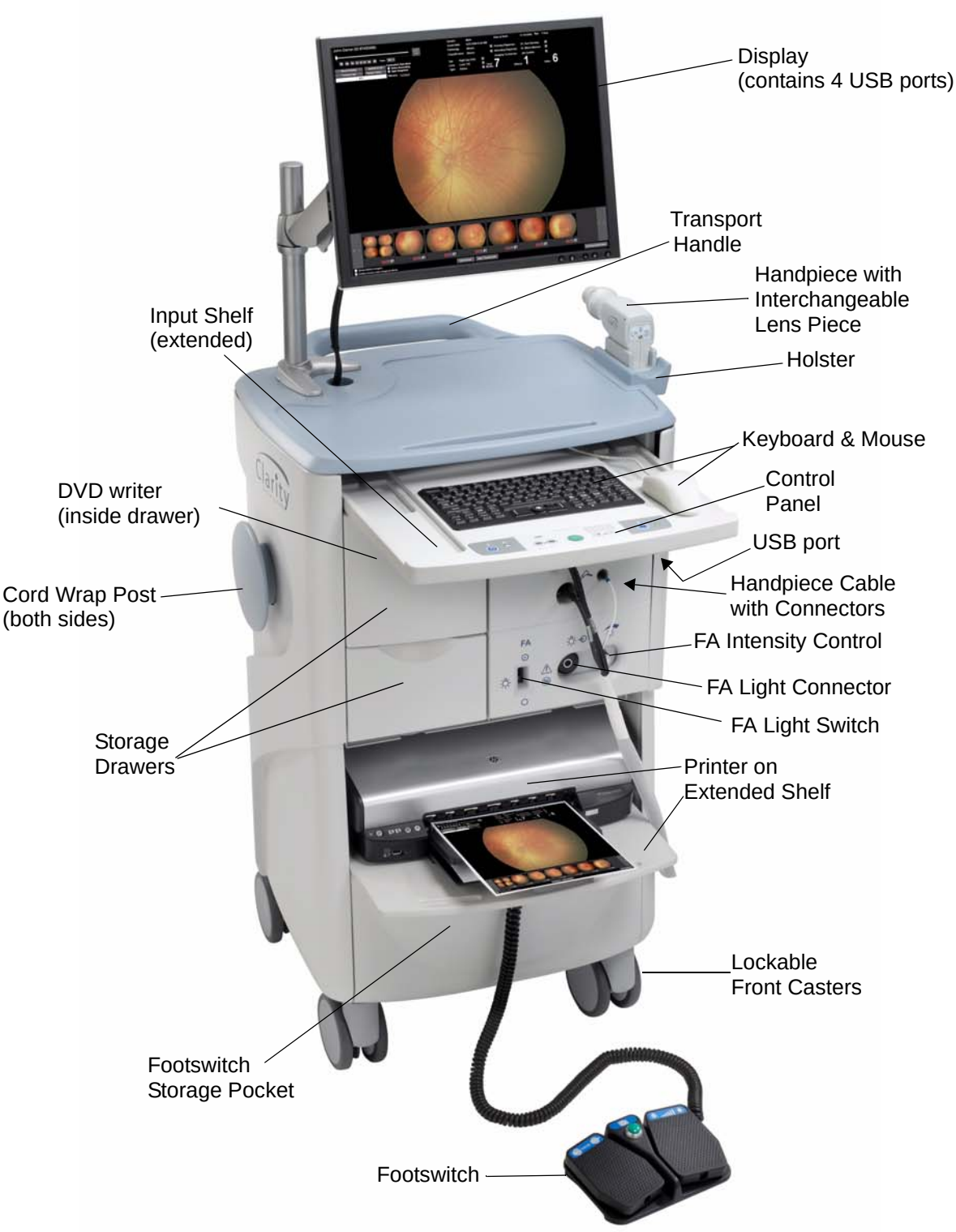


Figure 1 RetCam3 Ophthalmic Imaging System front view*

*Shown with optional FA (Fluorescein Angiography) feature

Figure 2 RetCam3 Ophthalmic Imaging System rear view

Main Hardware Components

- **Display:** A flat panel display is standard with the system.
- **Control Panel:** A membrane control panel turns the system on with one button, and has controls for illumination intensity, camera focus and snap (capture an image or start/stop video recording).
- **Handpiece:** Contains the camera. Lightweight and easy to position, it has a long cable for easy reach. Use with changeable lens pieces.

- **Chassis:** Contains the control systems and connections.
- **Footswitch:** Provides optional means to control illumination intensity, camera focus and snap.
- **Storage Drawers:** All units have two storage drawers for lens pieces, tools and supplies.
- **Fluorescein Angiography Source (optional):** An optional blue exciter light source is available for FA digital photography. It comes complete with a yellow barrier filter for the handpiece. You can adjust illumination intensity only through the FA intensity control.
- **Printer:** Color images and reports can be printed.

Figure 3 Handpiece and Lens piece

Lens Model	Application	Common Field of View
D1300	Premature Infant	130 Degrees
B1200	Standard Baby	120 Degrees
E800	High Contrast Children's & Adults	80 Degrees
C300	High Magnification	30 Degrees
PL200	Portrait Lens	N/A

Electrical Safety Information

The system has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Class I Type BF Electrical Equipment

Rated for Continuous Operation

Electromagnetic Emissions		
Compliance Level: Group 1, Class A		
Test Type	**Compliance Level**	**Notes**
Conducted Emissions CISPR 11/ EN 55011	Class A	The RetCam system uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions CISPR 11/ EN 55011	Class A	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
FCC Part 15B	Complies	

Electromagnetic Immunity		
Test Type	**IEC 60601-1-2 test and compliance level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients (AC Power) (I/O Lines) EN 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. AC Power electronic disturbances (transients) may cause the system's display to scroll continuously. If this occurs, imaging should not processed until the disturbance has ceased.
Surge Line to Line (AC Power) (I/O Lines) EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions EN 61000-4-11	>95% dip in Ut 0.5 cycle 60% dip in Ut 5 cycles 30% dip in Ut 25 cycles >95% dip in Ut 5 seconds	If the user of the RetCam system requires continued operation during power mains interruptions, it is recommended that the RetCam system be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated Immunity EN 61000-4-3	80MHz-2.5GHz 3V/m 80%@1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5 / E_1 \sqrt{P}$ 80 MHz to 800 MHz $d = 7 / E_1 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). E_1 is 3 V/m. Conducted Immunity: $d = (3.5 / V_1) \sqrt{P}$ where V_1 is 3 Vrms. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
Conducted Immunity EN 61000-4-6	0.15-80MHz 3 Vrms 80%@1kHz AC Mains	

WARNING: Interference may occur in the vicinity of equipment marked with the following symbol.

This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

An error message may be displayed, which then may require a system reset. To perform a system reset, press the system power switch on the control panel for ~6 seconds until the system powers down, then press the switch again to power the system back on.

WARNING: This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.

WARNING: To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

WARNING: For continued protection against risk of fire, replace only with same type and rating fuse.

Important User Safety Notices

1. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
2. DO NOT AUTOCLAVE any part of the device.
3. Appropriately power down and unplug the unit and allow the light source bulb to cool before replacing it.
4. Always return the handpiece to the holster when not imaging. You can drape the handpiece cable over the cord wrap post, but do not wrap it tightly or damage to the fiber optic may result.
5. Do not block access to the holster.
6. The system is not intended to be transported outdoors.
7. Newly acquired data may be lost if power is interrupted during live imaging.

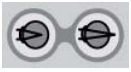
Note: backup battery power is available for at least 15 minutes after interrupt.

8. **The system comes protected from viruses, worms, and spyware with Microsoft's anti-malware. Please refer to your warranty prior to adding any additional software or contact Clarity Service.**

Labels and Symbols

System Power Switch

Focus



Focus Controls

Lamp Illumination

Intensity Controls

SNAP (capture) switch

Read instructions

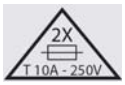
Caution:
Do not look directly into light source

Caution: Electrical hazard
High voltage in the FA unit

Chassis ground

Protective earth (ground)

Alternating current (AC)



System contains 2 fuses of indicated type.
Do not use any other type.

Backup battery

Computer network

Non-ionizing radiation

FA = Fluorescein Angiography

FA Intensity, increase clockwise

FA light OFF

FA light ON

Light source (fiber optic) connector

Handpiece connector

USB connector

Read accompanying user documentation

Fragile contents

This side of carton up

Temperature limits

Authorized representative in the EU

Type BF equipment (applied part is handpiece)

To prevent damage to lens piece, carefully store handpiece in holster when not in use.

Clean lens piece after use

Separate collection of waste at end-of-life as required by European directives. Contact Clarity for equipment disposal instructions.

European conformity

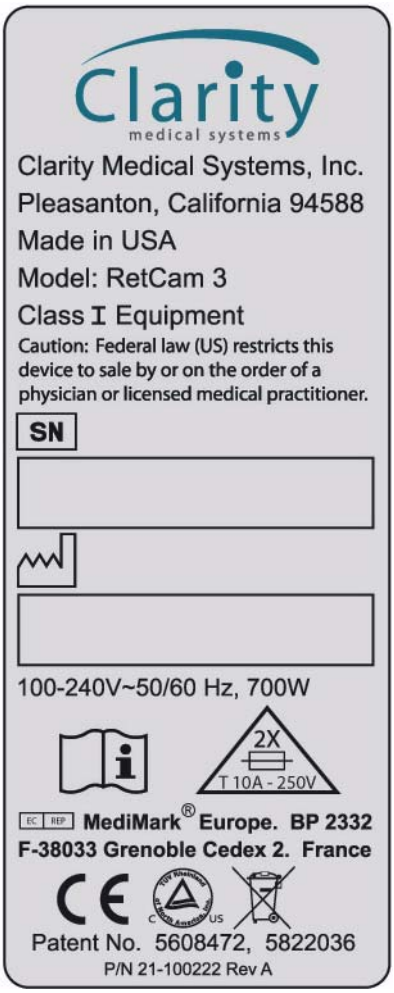
North American compliance certification

Serial number

Date of Manufacture

Keep away from the rain

Product Label


Clarity
medical systems
Clarity Medical Systems, Inc.
Pleasanton, California 94588
Made in USA
Model: RetCam 3
Class I Equipment
Caution: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.
SN
100-240V~50/60 Hz, 700W
2X
T 10A - 250V
EC REP MediMark® Europe. BP 2332
F-38033 Grenoble Cedex 2. France
Patent No. 5608472, 5822036
P/N 21-100222 Rev A

2 Using the RetCam 3

This chapter explains how to use the RetCam 3 system, after it is properly installed at your site. The activities described include:

- Turning the System ON (from Stand-by Mode) on page 19
- Turning the System OFF (Stand-by Ready) on page 21
- Using Hard Shutdown on page 22
- Turning OFF the Main Power on page 23
- Managing Patient Records on page 23
- Performing Exams on page 26
- Using Helpful Features on page 30
- Adding Exam Notes on page 33

Turning the System ON (from Stand-by Mode)

New systems are installed by Clarity trained personnel. The installation includes installing main power, attaching the handpiece, and adjusting the monitor. Upon request, full installation instructions are available from the Clarity Service Department. The instructions in this chapter are for using an installed system, which has the main power, printer, and monitor turned ON, the monitor height adjusted, and software installed and configured for the site.

Note: After software is installed, the system requires an Authorization key to initiate the system. The key is available through Clarity MSI service.

CAUTION: Never block any RetCam 3 System vents.

CAUTION: Never block access to the handpiece holster.

To turn the system ON from the Stand-by mode:

1. Carefully pull out the input shelf until it is fully extended.
2. Depress the System Power (Stand-by) button (located on the Control Panel) to turn ON system power. The System Power (Stand-by) indicator light (solid green) should be illuminated. The software should initialize.

The membrane control panel is located on the lower front part of the keyboard tray. It provides controls and indicators of system status.

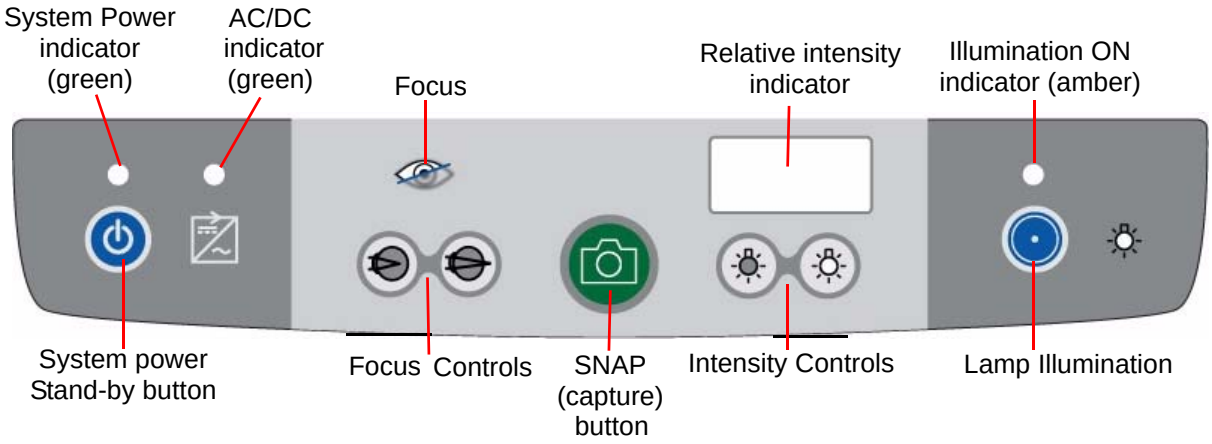
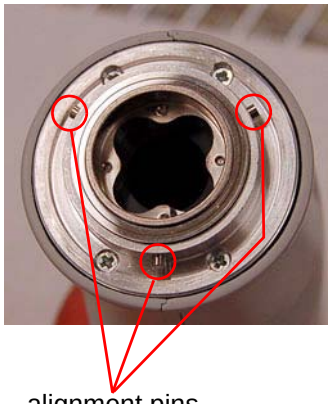
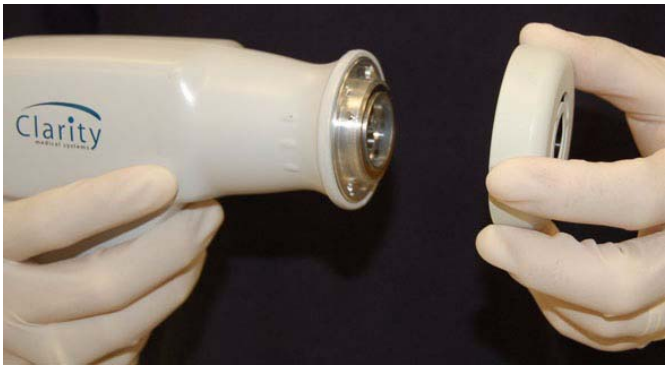


Figure 4 Control panel

3. Attach the desired lens piece to the Handpiece, as shown in Figure 5 and Installing Lens Pieces on page 21.



Align lens piece to fit over pins



Carefully tighten clockwise until it clicks in place. Do not overtorque.

Figure 5 Installing a lens piece on the handpiece

Installing Lens Pieces

A. Fit the lens piece on the handpiece, aligning the 3 radial pins on the front of the handpiece with the spaces between the tabs of the spring ring on the lens piece.

B. Twist the lens piece clockwise (as shown in Figure 5) until you hear a click, indicating that the lens piece is locked in place.

4. Verify that the handpiece is connected to the system as shown in Figure 6.

Figure 6 Handpiece connections

Always return the handpiece to the holster when it is not in use. You can drape the handpiece cable over the cord wrap post, but do not wrap it tightly or damage to the fiber optics may result.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT use if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

5. PRINTER. Extend the printer shelf fully and verify that sufficient paper is installed in the printer. The shelf can be pushed back in.
6. When the software is ready, you will see the message “Not Displaying Patients.”
7. For FA operation (if available) see Chapter 6, Fluorescein Angiography for instructions.
8. If the illumination lamp is OFF, press the illumination lamp button located on the right side on the Control Panel to turn illumination ON. The amber indicator light is illuminated when the lamp is ON.

Turning the System OFF (Stand-by Ready)

Note: We strongly suggest that you backup and store your data prior to turning OFF the system. See Exporting Images on page 43 for details.

1. To turn OFF the system (leaving the Stand-by Ready) hover over the red **Shutdown** button at the bottom of the Patients and Exams screen.

Figure 7 Shutdown button

The shutdown options screen appears. Select **Shutdown Computer**.

2. If the system stops responding, wait at least one minute because it may be busy. If the system does not respond after one minute, depress the System Power button (on the Control Panel) once.
3. All Control Panel indicators except for the green AC/DC indicator will turn off.
4. If FA is available, verify that the FA light switch is OFF.
5. Remove the lens from the handpiece. Carefully inspect and clean the lens piece. Store the lens in the lens box.
6. Return the handpiece to the holster.
7. Return the footswitch to the footswitch pocket (See Figure 8).

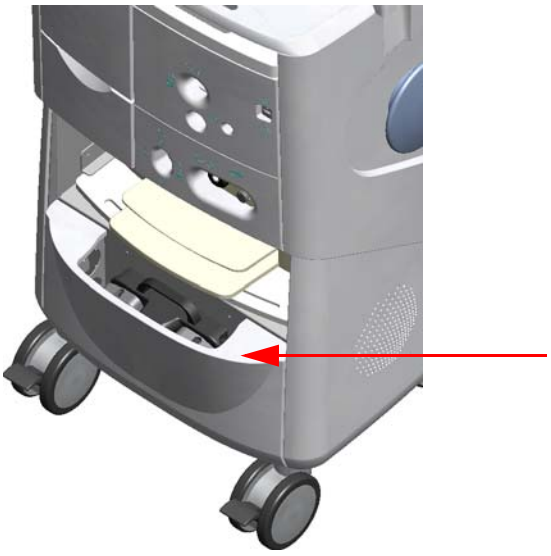


Figure 8 Footswitch pocket

Note: To re-start the system, see Turning the System ON (from Stand-by Mode) on page 19.

Using Hard Shutdown

WARNING: Do not use the hard shutdown method unless necessary because data corruption can occur.

In the event that hard shutdown is required, continuously press the System Power button on the control panel for at least 6 seconds to force the system, including the backup battery, to shut down.

Turning OFF the Main Power

Flip the main power switch (located on the rear of the system) to OFF. All Control Panel indicators will be OFF except the AC/DC indicator. The AC/DC indicator will flash green while the backup battery continues to supply power (at least 15 minutes).

Managing Patient Records

This section describes how to add a new patient and locate the records for an existing patient.

The software is ready to use when you see the start screen shown in Figure 9.

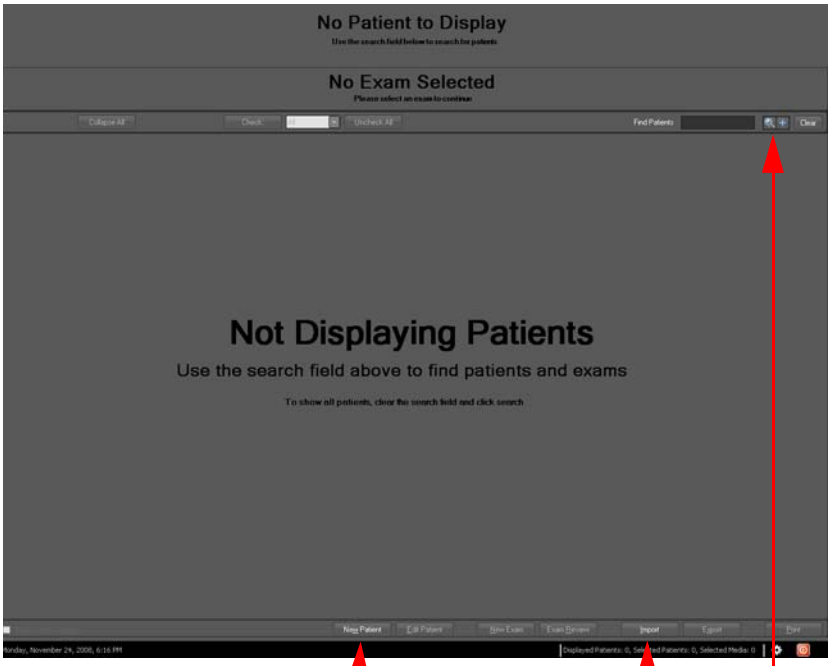

No Patient to Display
No Exam Selected
Not Displaying Patients
Use the search field above to find patients and exams
Add a new patient
Import data from CD, USB, network, etc.
Find existing patients

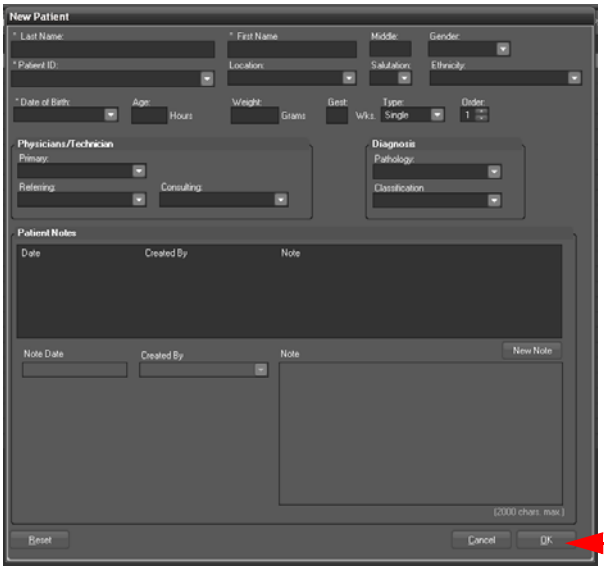
Figure 9 Start screen

Add a New Patient Record

To create a new patient record, the following information is required:

- First Name
- Last Name
- Date of Birth
- Patient ID

Patient information is repeated in several of the screens. The patient name and Patient ID are always shown in the upper left corner of every screen.



Click OK to proceed.

Enter information manually or use menus, where available.

Figure 10 Add new patient screen

Editing a Patient Record

Highlight the patient's record from the Patients and Exams screen.

Select Edit.

You can edit the following information:

- First Name
- Last Name
- Gender (Male, Female, Other, or Unknown)
- Date of Birth
- Weight (in grams)

Note: Any fields on the Edit Patient Screen are editable.

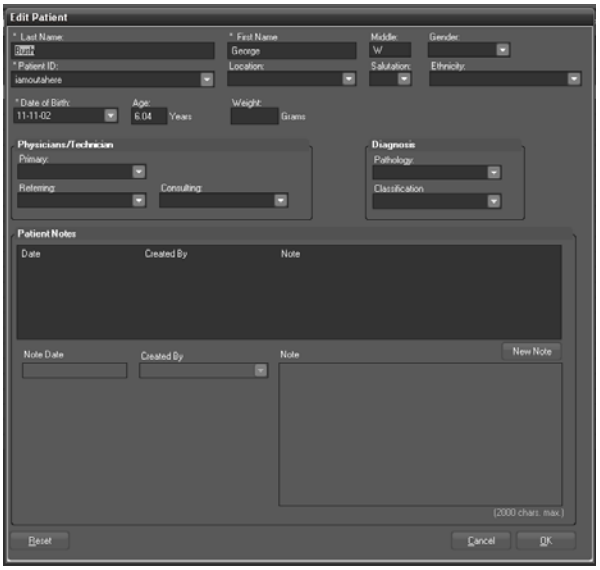


Figure 11 Edit patient record screen

Finding Existing Patient Records

You can search the directory to locate specific patient records.

Figure 12 Search buttons

From the Start screen, click the icon to display the entire patient directory or click the plus sign to locate patient records using one or more of the search features (see Figure 13).

Figure 13 Patient search options

Click **Clear** to clear all search fields.

Search Results

When you click the to display the entire patient directory, the results are displayed as shown in Figure 14.

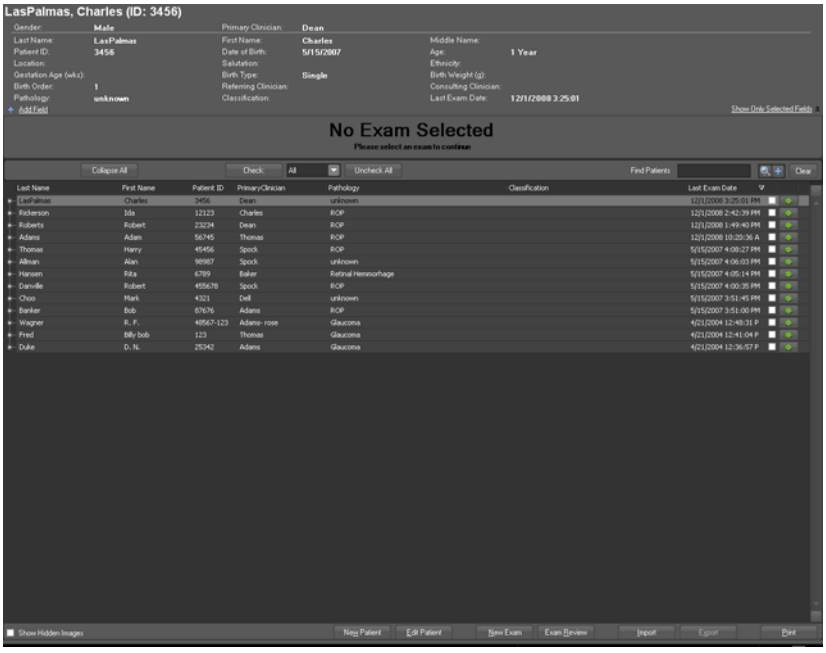


Figure 14 Patients and Exams Screen (Patient Directory)

From the Patients and Exams Screen, you can use the buttons shown in Figure 15 to sort the results.

Figure 15 Patients and Exams screen navigation buttons

Performing Exams

You can use the RetCam 3 to capture still images or video after selecting a patient. Click the green arrow on the right side of a patient name, or select the New Exam button. To start an exam, you can select a Preset Configuration, which can be easily edited, or Manual Configuration.

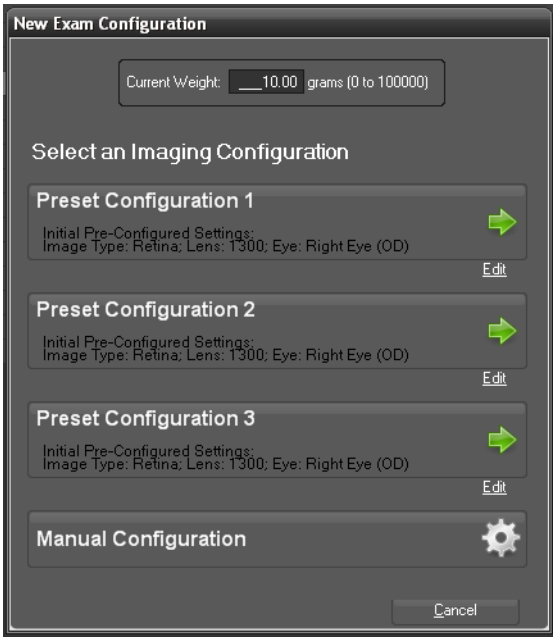


Figure 16 New Exam configuration screen

The following Information can be defined in the Preset or Manual Configuration:

Image Type	Lens	Eye
Retina	300	Right (OD)
Fluorescein Angiography	800	Left (OS)
Anterior Segment	1200	Unspecified
Unspecified	1300	
	Unspecified	

Once the new exam is configured, select the green arrow to the right to enter the New Exam screen.

Select **Show Thumbnails** at the bottom of the Exam screen to maximize the available features.

Figure 17 Show Thumbnails button

0 The **Show Thumbnails** button toggles between **Show Thumbnails** and **Hide Thumbnails**.

Capturing Still Images

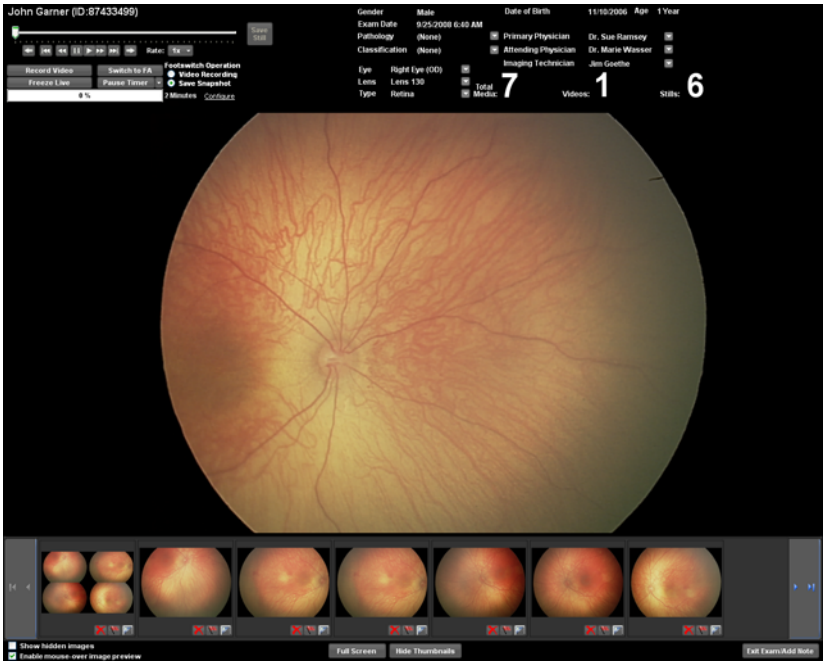


Figure 18 Still image screen

The recommended procedure is to capture video of the entire exam, and grab still images from the video then delete the video prior to exiting still image session after the exam is finished. You can take still images from the New Exam screen using the following:

Keyboard and Mouse

Some utility buttons are displayed on the monitor; use the mouse to select them.

Figure 19 Onscreen capture controls

Use the “S” key to SNAP images.

Footswitch

Select **Save Snapshot** from the monitor display (see Figure 21 on page 28). Then use the footswitch SNAP button to SNAP images.

Control Panel

Press the SNAP button.

Note: Saving video can take significant time and consumes a great deal of disc space. To maintain optimal system performance, select the images of interest from the video then delete the video prior to exiting Image Capture.

Note: The storage capacity of the system hard drive is a maximum of approximately 250,000 still images. Saving a combination of videos and stills will affect the total number of each that can be saved. Saving images with annotations reduces the total number of images that can be saved.

Note: If the Control Panel (or keyboard) controls do not respond, check that the Footswitch Controls are not activated.

Capturing Video

Up to 2 minutes of Video capture is available per session. A progress bar is enabled each time video is started to let you know the percentage of time used.

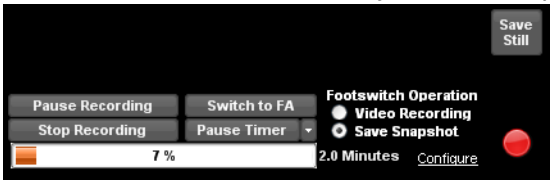


Figure 20 Progress bar

Video is captured at full resolution, 30 frames per second.

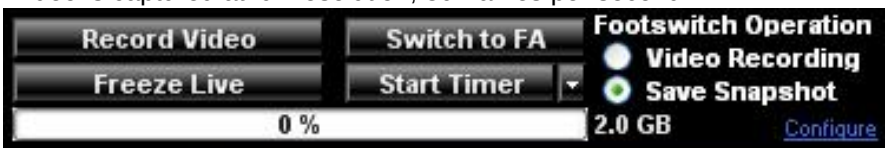


Figure 21 Video and image capture controls

The following controls are available on screen:

- **Record Video**—Starts recording video; to stop recording video, click **Stop Recording** or **Pause Recording**.
- **Freeze Live**—Freeze an image during image capture.
- **Switch to FA**—Change the image type to Fluorescein Angiography. See Chapter 6, Fluorescein Angiography.
- **Start Timer**—Start a timer to record the time elapsed during the exam.
- **Save Still**—Saves a still image to the hard drive
- Footswitch Operation options:
  - Use the SNAP button to pause and continue video recording.

Note: The storage capacity of the system hard drive is a maximum of 140 minutes of total video (for example, 70 videos of two minutes duration each,

or 280 videos of 30 seconds each). Saving a combination of videos and stills will affect the total number of each that can be saved. Saving images with annotations reduces the total number of images that can be saved.

Video Playback

When you stop live recording, the playback buttons are enabled.

Reverse, pause, and play

Fast forward

Go to the beginning of the recorded video

Go back one video

Advance one video

Go to the end of the recorded video

Control the rate of playback or search.

0 **Tip:** Using the left and right arrow keys on the keyboard will also move the video back or forward one frame at a time.

Deleting a Video

To delete a video, in the thumbnail view, click the **delete** icon (red “x”) at the bottom of the frame. This marks the video for deletion when you exit the exam. The **delete** icon toggles, that is, clicking it again before exiting the exam means the video is no longer marked for deletion.

+ **Note: Images and video can be selected for deletion only during the imaging session. Once the session has been exited, the images will be saved for that session.**

Using Helpful Features

The RetCam 3 software includes some useful features to streamline your work.

Shortcut Keys

An underlined letter indicates a quick key. To use a quick key, press ALT and the letter key simultaneously.

+ **Note: Do not use Windows shortcut keys, for example Copy (Ctrl+C), Paste (Ctrl+V), Undo (Ctrl+Z), and others.**

Still Images From Video

During video replay, you can identify and save still images from the exam. There are three ways to locate and save a still image.

1. Scroll through the thumbnails, using the arrows at the right and left ends of the strip at the bottom of the screen.

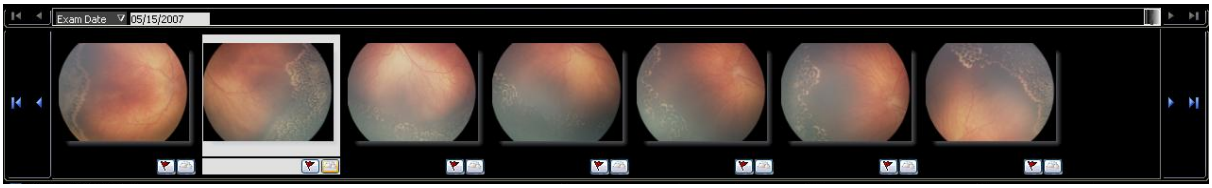


Figure 22 Video thumbnails

- Use the arrow at the right to scroll forward through the video and the arrow at the left to scroll back.
- Stop when the image you want to save is highlighted.
- With the image highlighted, click **Save Still** (or press **'S'** on the keyboard or press the **Snap** button on the footswitch).

2. Use the scrollbar at the top of the video controls to scroll through the video, and find a frame.

Figure 23 Video scrollbar control

- Move the slider to the right or left to scroll forward or back through the video.
- Stop the slider when you see an image you want to save.
- Click **Save Still** (or press **'S'** on the keyboard or press the **Snap** button on the footswitch).

3. Use the playback controls at the top of the screen to locate a still image:

- Start playback by clicking **Play** or **Reverse** **.**
- Click **Pause** when you see an image you want to save.
- Click **Save Still** (or press **'S'** on the keyboard or press the **Snap** button on the footswitch).

Changing Image Capture Options During an Exam

Before you start imaging, verify that the options displayed for eye, image type and lens piece are correct. If necessary, you can edit options from the image capture screen.

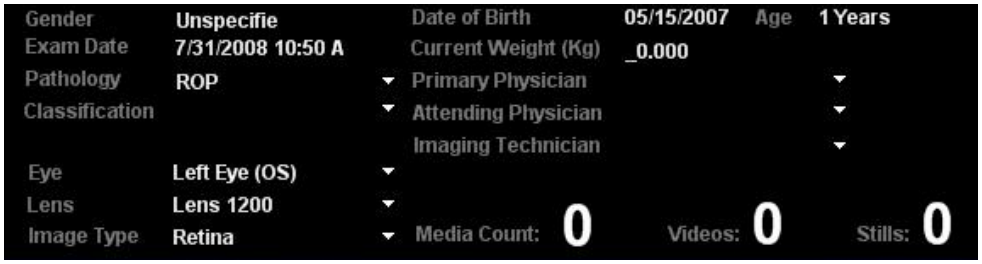


Figure 24 Select options for image capture

Changing Right Eye (OD) / Left Eye (OS)

To image the other eye in the same session, expand the **Eye** menu and select the other eye (**Right Eye (OD)** or **Left Eye (OS)**). The **Eye** selection is saved with the image.

Note: When using this option, be careful that you select the correct eye before you save the image. This is especially important when both eyes are captured in one video clip, and you save still images from the video. Make sure you select the correct eye before you save each still image from the video.

Note: Images and video can be selected for deletion only during the imaging session. Once the session has been exited, the images will be saved for that session.

Changing Image Type

Expand the **Image Type** menu to select **Retina, Anterior Segment,** or **Other** during an imaging session. All selections record the images in color. The Image type selection is saved with the image.

Changing Lens

You can also select a different lens piece during imaging. Expand the **Lens** menu to select **1300** (Premature Infant), **1200** (Standard Baby), **800** (Posterior), **300** (High Mag), or **Unspecified**. The lens piece selection is saved with the image.

WARNING: System power from a fully-charged battery is available for at least 15 minutes after an AC (main) power loss. In the event of an AC power loss, we strongly suggest that you complete the imaging session and save images to prevent potential data loss. Start a new live imaging session only after reconnecting the AC power.

Enable mouse-over image preview: Check this box to see an existing image on screen during a live imaging session.

Figure 25 Enable mouse-over

Adding Exam Notes

When you click the **Exit Exam/Add Note** button at the bottom right corner of the image capture screen, the Exam Notes dialog appears. For each eye, it provides a field where you can type in notes.

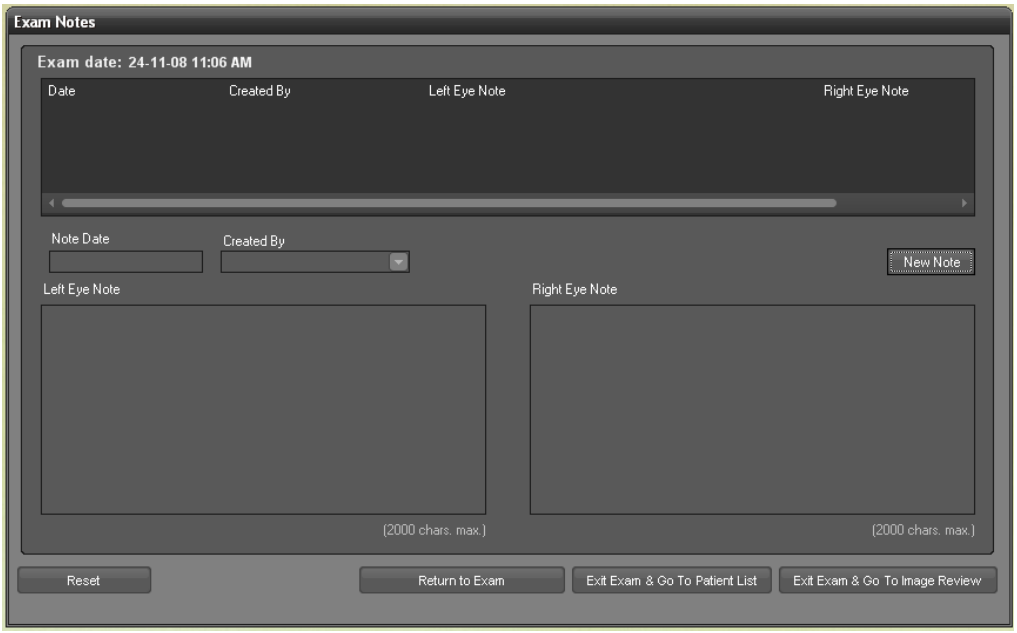


Figure 26 Exam Notes dialog

To add notes:

1. Click **New Note** to activate the notes fields.
2. Type new notes in the fields titled Left Eye Note and Right Eye Note.
3. Click **Save Note** to add notes you have typed to the notes above.

Note: You cannot change a note after you click Save Note.

- Click **Reset** to clear all fields.
- Click **Return to Exam** to return to Live Imaging.
- Click **Exit Exam & Go to Patient List** to return to the patient list display.
- Click **Exit Exam & Go to Image Review** to return to the image review screen.

You can add notes also from the Review screen. Once saved, the text cannot be modified. You can append text to notes from the Review, Compare, and Image Process screens by clicking **Exam Notes**. Notes are identified by date/time and person creating the note.

3 Review and Compare Images

Having acquired images, they are available for review and comparison This section covers the following topics:

- Review Screen, below
- Compare Mode, page 38

Review Screen

The Review screen appears optionally when you exit live imaging. You can also access it by clicking the Exam Review button on the patient list screen.

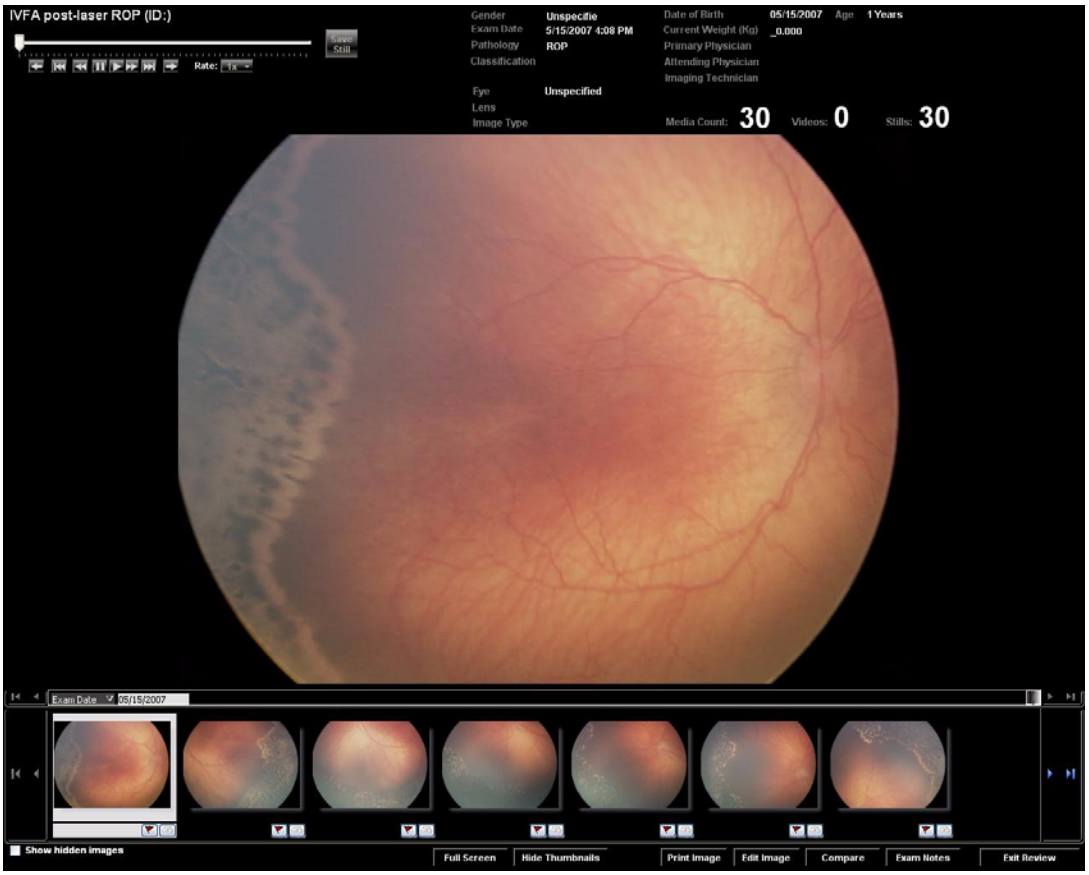


Figure 27 Exam Review screen

When you exit live imaging, the Review screen displays the images acquired in the session just completed. When you access the Review Screen by other means, it displays the images for the last patient and session you selected. To review exams for a different patient, exit to the Patients and Exams page, and select another patient.

By default, thumbnails for all images acquired in the selected session appear along the bottom of the screen.

Video playback controls appear in the upper left corner of the screen.

The currently selected image (the first one by default) appears full size. Click on a thumbnail to display the full resolution image. You can use the arrows at the left and right edges of the thumbnail strip or the up and down arrow keys on the keyboard to scroll through the thumbnails or select a thumbnail.

Thumbnails of video clips show four images (first, last, and two intermediate images in the video) in the quadrants of a square.

Click on the thumbnail to bring the video to the display area. Use the video playback buttons to control the video. The buttons have the same functions as for live imaging. Click **Play** to start playing video.

The following options are available on the Review Screen:

Exam Date

Select a different exam to review by clicking the arrow next to **Exam Date**.

Show Hidden Images

Default is unchecked, in which case only thumbnails of non-hidden images are displayed. When this box is checked, thumbnails for hidden images appear and are available for full size viewing.

Hide Image

Click the **Hide Image** icon below the highlighted thumbnail to hide the current image. You can click this icon beneath any thumbnail to hide that image. You can use the icon to toggle between hidden and unhidden. Hidden items are not deleted. Their thumbnails do not appear unless the **Show hidden images** box is checked.

Unhide Item

When **Show hidden images** is checked and you click on the thumbnail of a hidden image, the **Hide Image** button toggles to **Unhide Item**, which you can click to make the image available again for full size viewing.

Flag Image

Click the **Flag Image** icon to flag the current image as an image of special interest. A small red flag appears at the top left corner of the thumbnail. To unflag an image, click the icon again. The icon toggles between flagged and unflagged.

Full Screen

Click **Full Screen** to display a full screen view of the current image, with no thumbnails visible.

Hide Thumbnails

Click **Hide Thumbnails** to remove the thumbnail display without changing the display of the current image.

Print Image

Click **Print Image** to print the current image displayed.

Edit Image

Click **Edit Image** to edit the current image.

Compare

Click **Compare** to view two images side-by-side on the screen. See Compare Mode for details.

Exam Notes

Click **Exam Notes** to review or append text to the session notes in the Review screen. You cannot alter saved notes. Notes are identified by date and created by.

Exit Review

Click **Exit Review** to exit the current review session and return to the Patients and Exams screen.

Compare Mode

The Compare screen appears when you click **Compare**. Use the Compare screen to compare any two images. You can compare images for one or more exams for a single patient.

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Figure 28 Compare [Images] screen

The last image displayed on the Review screen will appear on the left side of the Compare screen. On the right side, by default, the first image of the first session for the same patient appears. Identifying information for each image appears above it. Below each image at the bottom, thumbnails appear for all images in the same session. The Exam Selector displays the dates for all the current patient's exams above the thumbnails. The highlighted date is the exam date for the current thumbnails. To view images from a different exam, select another exam date from the Exam Selector.

The video playback controls are not displayed on this screen because It is not possible to compare videos.

The following controls, available on the image display screen, are not available on the Compare screen:

- **Hide Image** and **Flag Image** icons
- **Full Screen**
- **Hide Thumbnails**
- **Compare** (This button is replaced by **End Compare** on this screen.)

The Compare screen provides buttons for the following options:

Show hidden images

The check box for displaying hidden images is available.

Print Image

Click **Print Image** to print the two images displayed on this screen, one above the other.

Edit Image

Click Edit Image to display the Image Adjustment window.

End Compare

Click **End Compare** to return to the display of a single image.

Exam Notes

Click **Exam Notes** to review or append text to the exam notes for that image. You cannot alter saved notes. Notes are identified by date and the doctor's name.

Exit Review

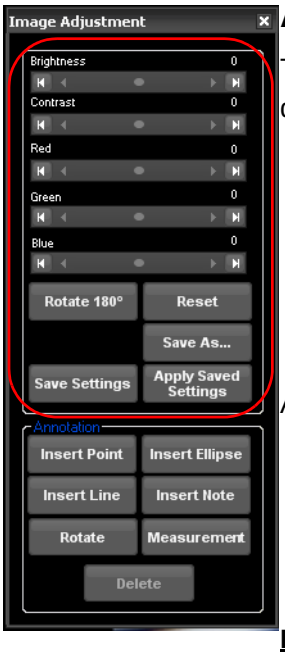
Click **Exit Review** to return to the Patients and Exams screen.

Image Adjustment

To adjust an image, select the image from the Exam Review screen and click **Edit Image**.

Figure 29 Edit Image button

The Image Adjustment window appears. The upper portion of this window provides image adjustment tools. The low portion of this window provide tools for annotating an image. To exit the Image Adjustment window, click the "X" in the upper right corner of the window.



Adjust Image Display Parameters

The right side of the Process screen provides controls to adjust the following image display parameters:

- **Brightness**
- **Contrast**
- **Red**
- **Green**
- **Blue**

All parameters have a default setting of zero (0), and range from -100 to +100.

- Each click on the right or left arrow at the end of the slider bar changes the parameter value by 1%.
- Each click on the bar to the right or left of the slider changes the parameter value by 1.

Rotate 180º

Click this button to rotate the image 180º.

Reset Button

Click **Reset** to reset all display parameters to zero.

Save Settings

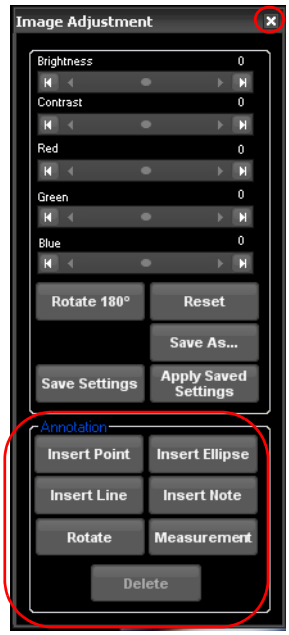
Click to save the current settings for **Brightness, Contrast** and **Red, Green** and **Blue**. The saved settings can be applied when you select **Apply Saved Settings**.

Apply Saved Settings

Click to apply the currently saved settings for **Brightness, Contrast** and **Red, Green and Blue**. Image display adjustments are applied to all images in the current image processing session, until you save new settings or click the **Reset Adjustments** button, which resets all parameters to zero.

When you leave the current session, the display settings are reset to zero.

Note: Images you save from the Process screen will reflect image display adjustments (and all other changes) you make, but the original images in the database will not be changed.



Annotating Images

You can annotate an image by inserting graphic elements or text notes.

Click to select any of the following annotation features:

- Insert Point—Insert pointer and text on the image.
- Insert Ellipse—Draw an ellipse on the image.
- Insert Line—Draw a line on the image.
- Insert Note—Add text to the image.
- Rotate—Rotate the pointer.
- Measurement—Display the number of pixels between two points.
- Delete—Remove a selected annotation.

Select the “X” at the top right to close the screen.

Note: The original images in the database are never changed, even when you modify the image displayed on the screen. You can save processed images only outside the RetCam database and in a non-proprietary format.

4 Import and Export Images

You can import or export images:

- To make RetCam data available on other RetCam stations, which include RetCam3, RetCam II and RetCam Shuttle systems, and PCs running RetCam Review Software.
- To make a backup copy of the original image data kept on the hard drive.
- To view with standard image software.
- To use RetCam images with third party imaging systems.

Backing Up Images

The RetCam system stores all images to the local hard drive. It is highly recommended to create a central repository on a network of all data from the RetCam device for long term data backup.

Recommended Backup Frequency: Each day you acquire new images.

Exporting Images

You can export data to any accessible location. There are three general steps to complete export. These are:

1. Select Images for Export, below
2. Select Export Options, page 45
3. Complete Export, page 47

Select Images for Export

1. Go to the Patients List screen and highlight the desired patient. Click the arrow on the left side to show all the exams for the selected patient.

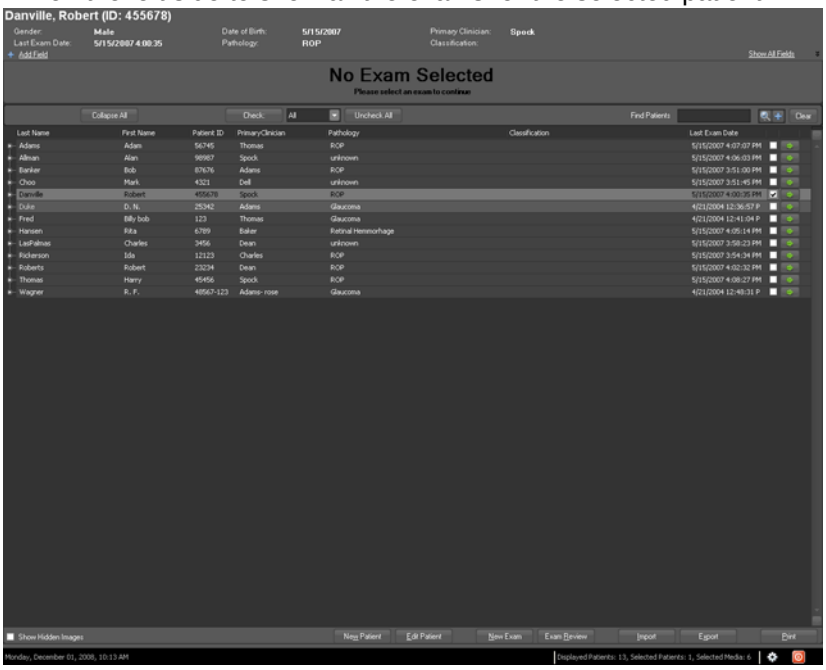


Figure 30 Select patients and exams for export

2. Check the white boxes on the right side of the display to select files for Export. You can select **Check All** to select all patients' records and exams.
3. Click the **Export** button at the bottom of the screen.
4. The **Export** dialog appears.

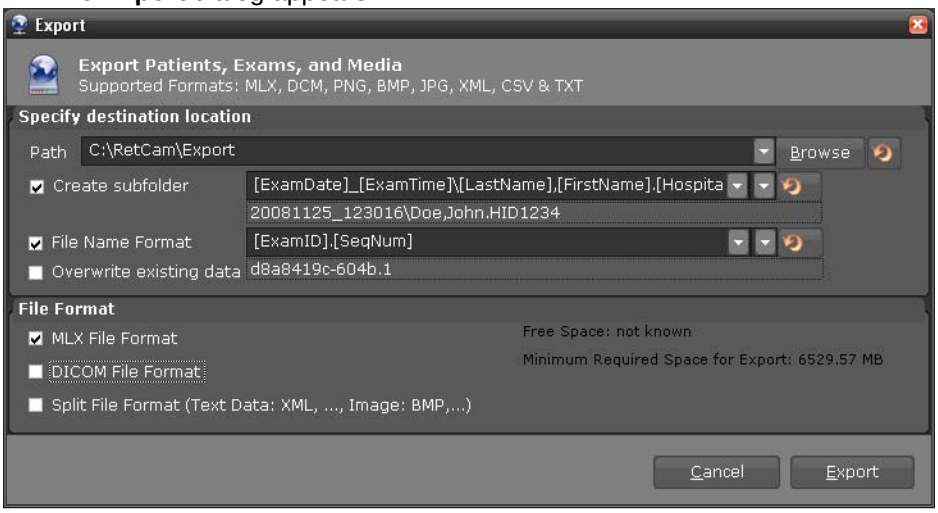


Figure 31 Export dialog

By default, the dialog shows the source location path and options used for the last export.

Note: The Minimum Required Space for Export is displayed. Verify that the export destination has sufficient free space to accept the exported files.

Note Regarding File Size Capacity: We recommend that you do not export more than 2000 images in one batch, because the export will take a long time. We recommend that multiple smaller transfers be executed.

Select Export Options

1. To change the destination location path, select the arrow to expand the path list or click **Browse**. Clicking the red reverse arrow resets the source location to the default setting.

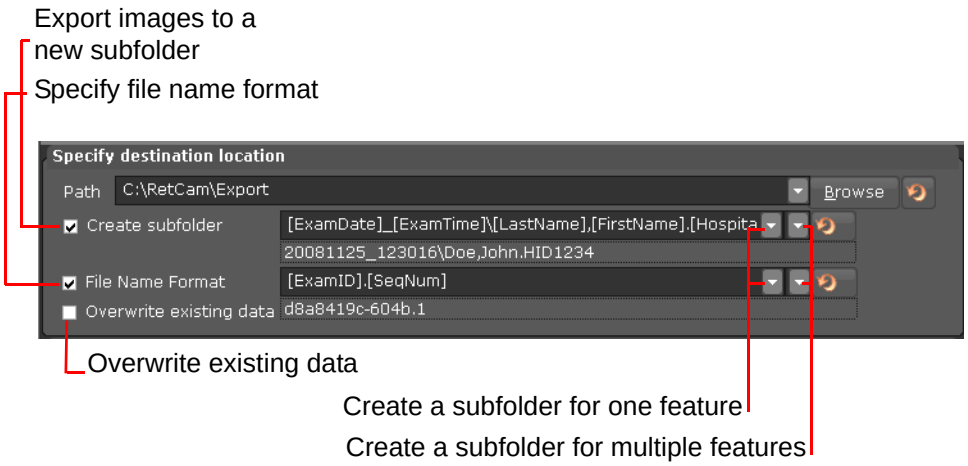


Figure 32 Export destination options

2. Select the destination options:
   - Export images to a new subfolder.
   - Create a subfolder for one feature, such as exam date, exam time, last name, etc.
   - Create a subfolder for multiple features.
   - Specify a file name format for the exported files.
   - Overwrite existing data.

Select the File Format

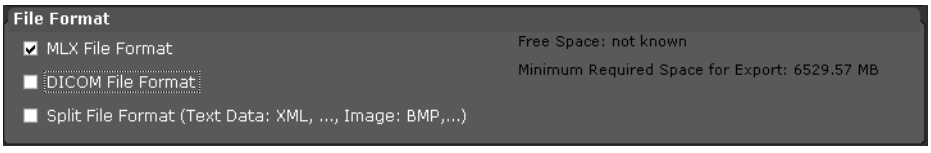

File Format
MLX File Format
DICOM File Format
Split File Format (Text Data: XML, ..., Image: BMP,...)
Free Space: not known
Minimum Required Space for Export: 6529.57 MB

Figure 33 Select file format

Select MLX, DICOM, or Split File format.

MLX	Clarity's proprietary encrypted data format
DICOM (DCM)	DCM is the filename extension for patient data files that are compatible with the DICOM (Digital Imaging and Communications in Medicine) standards for ophthalmology.
Split File Format	If you select this format, you will have additional options for the Export Image and Export Data formats.

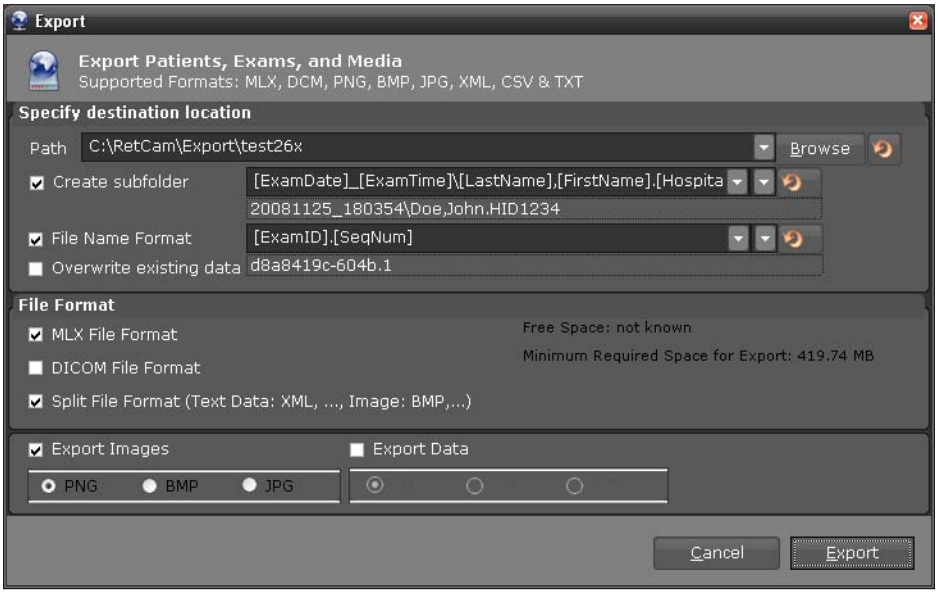


Figure 34 Select image and data format

Export Image Formats

PNG	Portable Network Graphic uses compression to reduce file size (about half the size of a bitmap file), but without loss in quality or resolution. It can be viewed in a standard web browser and used in image processing or viewing applications.
BMP	The bitmap format saves images at full resolution without any quality loss. It results in the largest files.
JPG	(or JPEG) This format uses compression to reduce file size, which results in loss of resolution or quality in proportion to the amount of compression. You can select the image quality before you save.

Export Data Formats

XML	Extensible markup language format
CSV	Comma separated values format
TXT	Generic text format

Complete Export

Select **Export** to initiate Exporting or **Cancel**. A dialog opens to show export progress.

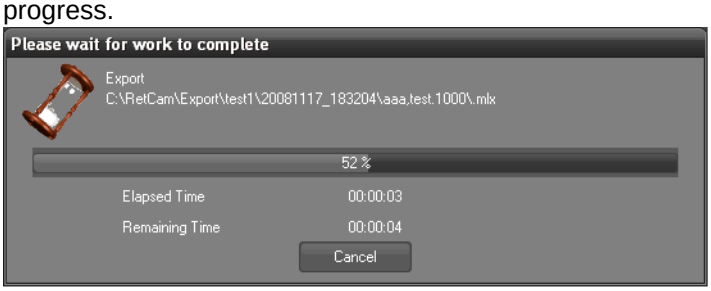


Figure 35 Export progress dialog

Importing Images

Except for data backup, the export destination on the network is an intermediate location. To complete the data transfer and make the images available for viewing on another RetCam system, you must use the RetCam software to import the transferred images into the target system database.

WARNING: Never connect the RetCam3 to a network or any externally powered devices or peripherals *during imaging*.

Note: We recommend that you do not import more than 2000 images in one batch, because the import will take a long time. One way to limit batch size is to import only the files from which you (or someone else) exported a limited number of images. In general, we recommend you import images from one patient at a time.

Follow these steps to import RetCam images:

1. On the screen shown in Figure 36, click **Import**.

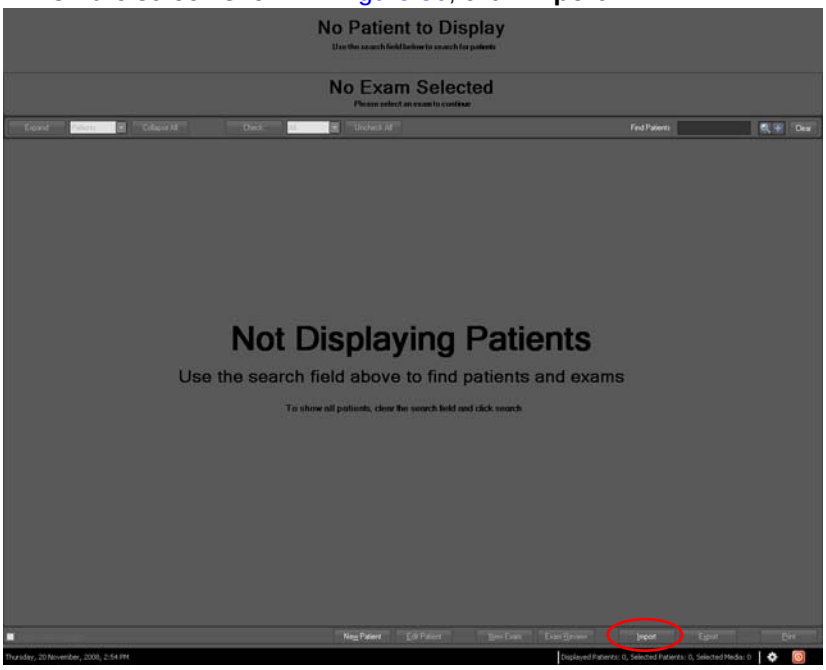

No Patient to Display
No Exam Selected
Not Displaying Patients
Use the search field above to find patients and exams
Import

Figure 36 Start screen

The Import Folder dialog appears

.

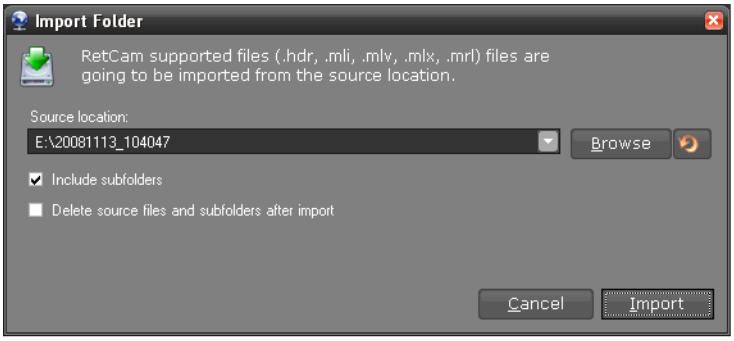


Figure 37 Import Folder dialog

By default, it shows the Source location path and all the options last used.

2. To change the source location, select the arrow to expand the path list or click **Browse**. Clicking the red reverse arrow resets the source location to the default setting.
3. Once the desired Source location is showing, you can select import options.

Included subfolders check box

Select this check box if you want to import images in all subfolders of the source location. If not selected, you will import only the files found in the source location folder itself, and no images in its subfolders. If you want files from a specific (patient) subfolder only, select that subfolder as the Source location.

Delete source files and subfolders after import check box

To manage the size of the export destination, select this check box to delete the source files and subfolders after import is complete.

Note: Do not select this check box if you or others want to import the same data to another RetCam station, which would be the case especially if you are importing from the backup repository.

Note: This does not affect any working RetCam database, but only the intermediate location where files are exported to and imported from.

4. Click **Import** to initiate importing, or **Cancel**. A dialog opens to show import progress.
5. A **Select Import Data to save** dialog will appear. If not all items were imported, you may select **Show Detailed Log** for the explanation. It could be because some files are duplicates (already in the destination database), or the file is not found, or it is corrupt, or the destination is write-protected.

View imported data and select thumbnails you need to save. Select **Import Selection**. You can also select **Import All** to save all images.

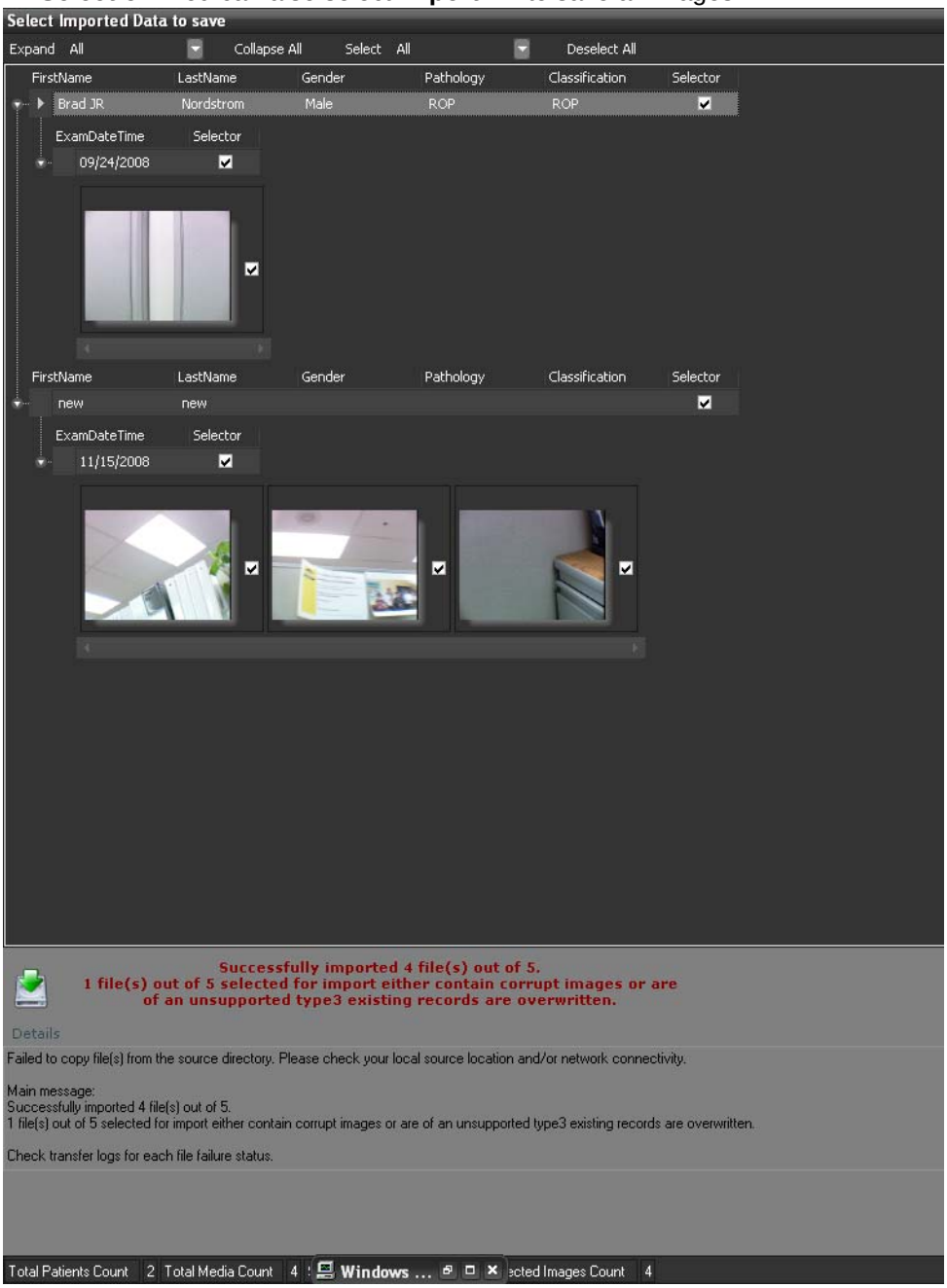


Figure 38 Import successful

The system will notify you when the import is completed successfully.

5 Printing Images

The **Print** button appears at the lower right of screens when printing is available.

Note: Print is only available if there is a printer attached to the system, either directly or through the network, if so connected.

WARNING: Never connect the RetCam3 to a network or any externally powered devices or peripherals *during imaging*.

You can **Print Images** from the:

- **Exam Review Screen**
- **Compare Screen**
- **Patient list (or Patients and Exams screen):** Print images, reports, or both

The default image size is 5" x 7." For optimal resolution, Clarity recommends printing images 5" x 7" or smaller. This also avoids the rapid depletion of printer ink.

Printing Images and Reports

You can print both images and reports from the patient list (or Patients and Exams screen):

1. Select (or highlight) patient.
2. Check the desired session, patient, or image.
3. Select **Print**.

The following dialog appears:

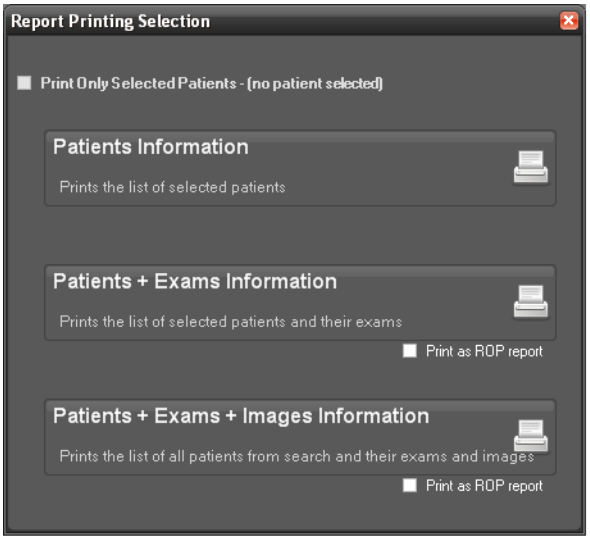

Report Printing Selection
Print Only Selected Patients - (no patient selected)
Patients Information
Prints the list of selected patients
Patients + Exams Information
Prints the list of selected patients and their exams
Print as ROP report
Patients + Exams + Images Information
Prints the list of all patients from search and their exams and images
Print as ROP report

Figure 39 Print dialog

Select the desired option(s).

+ **Reports are formatted to fit on US letter size or A4 paper.**

Recommended Supplies

Clarity sells printer supplies - photo paper and ink - for the printer supplied with the system.

+ **Note: Network printers used with the system must have a printer driver supported by Windows XP.**

+ **Note: Be aware that you must change the paper in the printer when switching between printing images and reports.**

See the User Preferences section for information on setting printer defaults.

6 Fluorescein Angiography

This chapter covers acquisition of still or video images using the fluorescein angiography (FA) option. These functions are provided through the Image Capture screen.

Theory of Operation

The FA generates a narrow-band blue excitation light centered at approximately 471 nanometers. The barrier filter inserted in the handpiece has a cutoff wavelength at 510 nanometers or shorter. The FA dye absorbs the blue light and emits green light longer than 510 nanometers, so the RetCam3 camera can image the green fluorescence without being overwhelmed by the blue excitation light.

Using Fluorescein Angiography (FA) Mode

Note: The internal backup battery never powers the FA. Therefore, the system must be plugged into wall power to operate in FA mode.

1. Switch ON FA power. The FA lamp requires a few minutes to stabilize.

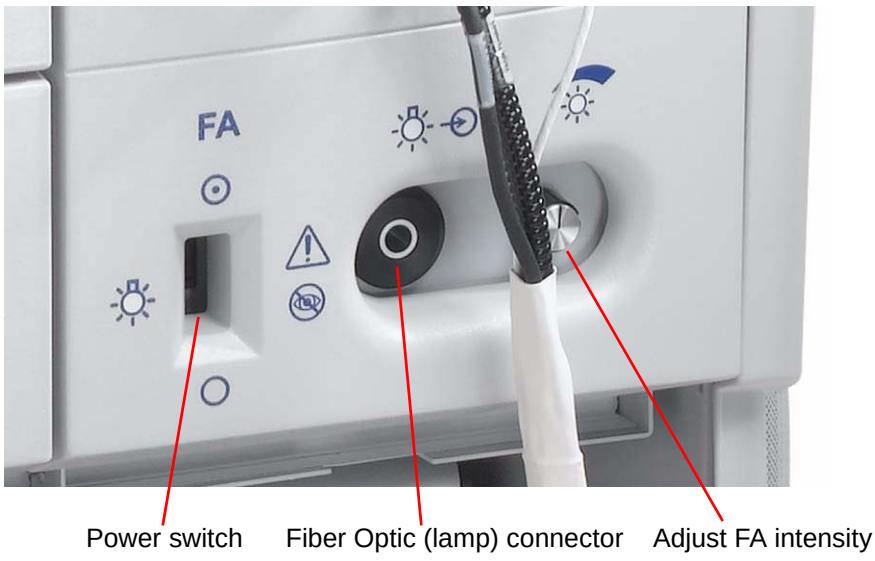


Figure 40 Front panel of FA

2. Carefully install the barrier filter into the handpiece:
   A. Remove the lens piece (if present).
   B. Insert the barrier filter into the cavity of the handpiece, observing the orientation as shown in Figure 41.
   C. Reattach the lens piece before moving the handpiece.

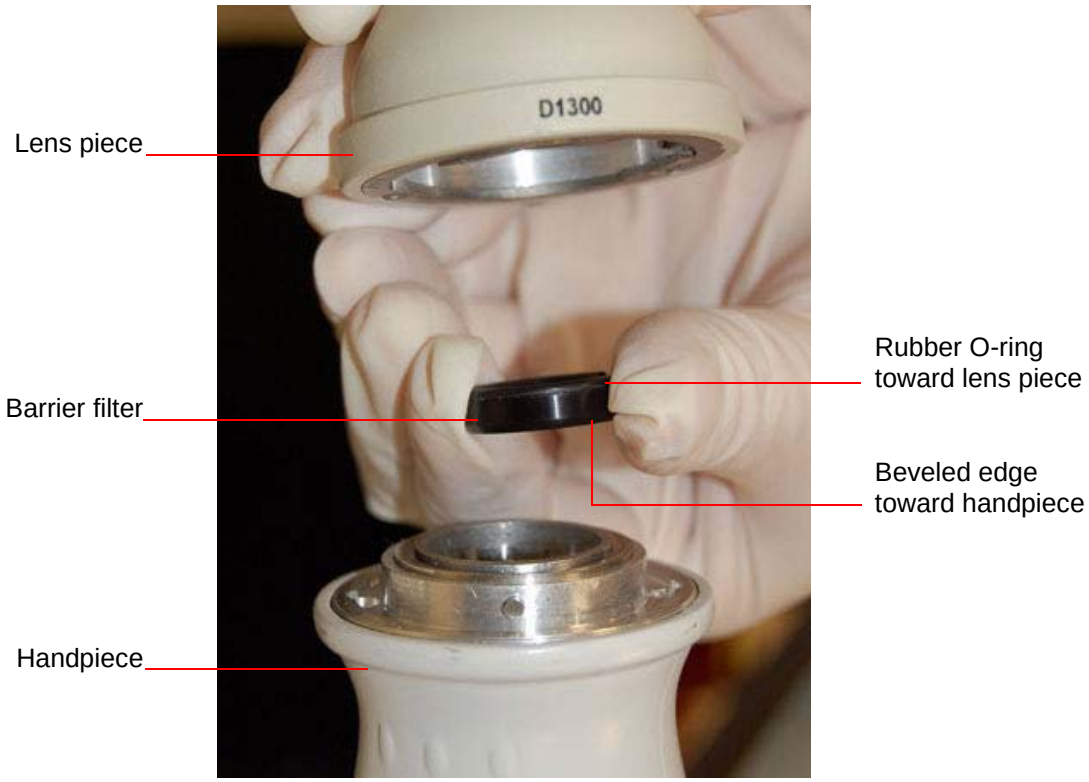


Figure 41 Barrier filter installation

Note: If lenses are exchanged during an FA session, hold the camera upright to avoid having the barrier filter fall out during the exchange.

3. Select Switch to FA from the live image screen and SNAP a “red-free” image (recommended).
4. Attach the fiber optic lamp connector from the handpiece into the FA fiber optic port. (See Figure 40.)
5. Select Start Timer. Dye can now be injected.

Note: The timer can be paused or stopped at any time.

6. Adjust FA light intensity using the FA intensity knob shown in Figure 40.

Note: You cannot adjust the FA lamp intensity using the footswitch or control panel controls.

7. You can take still photos or video during the FA session, and you can SNAP still photos during video replay.

8. When the FA session is completed:
   A. Stop the timer.
   B. Move the fiber optic cable back to the white light port and switch OFF the FA power.
   C. Remove and store the barrier filter in the special clear plastic box provided, or in a manner that prevents damage. Clean the filter with compressed air and optical cleaner and tissue as required.

When the Image Type selected is Fluorescein, the video and images are displayed and stored in grayscale by default.

+ **To view and store FA images and videos in color, select FA from the** Image Type **menu instead of using the Switch to FA button.**

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of light necessary; no greater than 5 minutes.

WARNING: Do not look directly at the fiber optic port.

WARNING: If the light from the illumination source is not blue DO NOT USE IT because there may be a filter failure.

WARNING: Do not attempt to override the interlock switches, or to operate in FA mode with the cover off. The FA contains internal sources of high voltage, high current, heat, and moving parts. Only authorized technicians may attempt any service or repairs to the FA. Failure to observe this warning could result in injury to operator or patient.

Configuring the FA Timer

To configure the FA timer, click **Configure** at the top left of the screen.

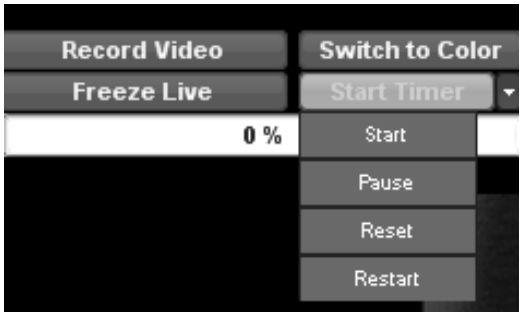


Figure 42 FA timer controls

The drop-down menu offers the following timer options:

- Start—Start the timer.
- Pause—Pause video capture, but keep the timer running.

- Restart—Restart the timer, following a stop or reset.
- Reset—Set the timer to zero again.

You can also configure the following options:

- Capture video and images in color or greyscale
- Set the frame rate
- Frame number
- Elapsed time

Tip: You can move the timer display to any location on the image capture window.

Tip: You can user the timer when you are not in FA mode.

Using Video Controls in FA Mode

When you are in FA mode, the timer is controlled separately from the video. For example, when you pause or stop the video, video capture is interrupted, but the timer continues uninterrupted.

When you pause video capture, the video images acquired up to that point are not yet saved to the hard drive.

Images are saved automatically to the hard drive when you stop video capture. The video display shows the percentage of the available 2GB hard drive space already used.

7 Maintenance and Support

This section addresses maintenance and support under the following topics:

- Recommended Maintenance Schedule, below
- Cleaning Procedures, below
- Fuse Replacement, page 68
- Replace Illumination Lamp, page 70
- Key Validation, page 72
- Technical Support, page 73
- Service Information, page 74

Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

> System powered for at least 8 hours (AC powered - AC/DC indicator ON light solid) to assure backup battery is fully charged.

Burned out bulb: Replace illumination bulb.

Blown fuse: Replace system fuses.

Cleaning Procedures

For cleaning purposes, the RetCam3 is divided into two categories:

- The Lens Piece that contacts the patient
- The rest of the system

Cleaning the Lens Piece

The patient contact area lens should be cleaned immediately after use to prevent the coupling gel from hardening.

1. Wipe away debris from the front lens piece surface with a soft dry tissue, sterile water soaked tissue, or combination.
2. Then, using a clean soft cloth (such as sterile gauze) saturated in a fresh solution of 70% IPA (isopropyl alcohol), gently wipe the front of the lens piece, being sure to pay special attention to the concave contact lens area, to remove any remaining debris; at least 11 wipes with a clean saturated cloth. Pre-packaged 70% IPA swabs (such as ReliOn Alcohol swabs or BD Alcohol Swabs) may be used.
3. Rinse surface thoroughly using sterile water.

4. Air dry.
5. Verify that the lens surface is free of debris and coupling gel. Repeat above steps if necessary.
6. Inspect the lens for damage and clarity. Do not use the lens if there are chips, cracks, or rough edges on the lens which may injure the patient's eye.

CAUTION: Do not autoclave any part of the system. Autoclaving causes irreparable damage and voids the warranty.

CAUTION: Never immerse the entire lens piece or handpiece in any liquid or solution. If necessary, only the distal 4 mm can be immersed. See Figure 43. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

WARNING: If you clean or disinfect, rinse the lens with sterile water to avoid corneal de-epithelialization that may be caused by residual solution.

Note: For disinfection, see attached Information Statement from the American Academy of Ophthalmology.

CAUTION: As disinfection solutions may cause corrosion of the lens piece, soak times that exceed the recommendation should be avoided.

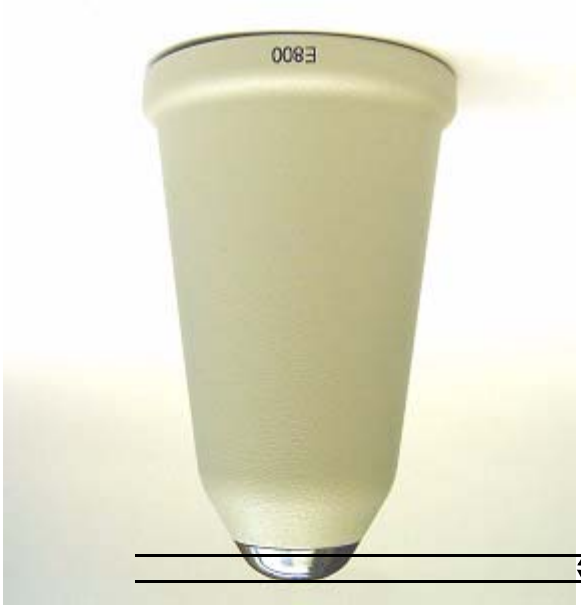


Figure 43 Inverted lens piece showing permissible depth of immersion

Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions on any part of the system.

Disposal of Materials

Dispose of waste materials according to local and national requirements. Contact Clarity Service if additional assistance is required.

Information Statement

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Minimizing Transmission of Bloodborne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms

Introduction

This document is intended to provide guidance to ophthalmologists and their staff about minimizing transmission of infection in their offices and operating rooms. This document addresses prevention of bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and other viruses, such as adenovirus and herpes simplex virus. These recommendations are mainly based on broad guidelines issued by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Labor for health care workers.

Bloodborne pathogens may be present in blood, blood-contaminated products or other bodily fluids especially if contaminated with or mixed with blood. Percutaneous injuries (e.g., a needlestick or cut with a sharp object) represent the greatest risk of transmission of bloodborne pathogens to health care workers. Universal precautions apply to blood and other body fluids containing visible blood, but not to tears unless they contain visible blood.[1] The use of universal precautions, including handwashing and barriers, reduces contact with blood and bodily fluids, thus reducing exposure of health care workers to bloodborne pathogens. The use of safety devices and techniques to reduce handling of sharp instruments also reduces the number of percutaneous injuries.

Exposure to HIV in health care settings has been of major concern. As of June, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 56 U.S. health care personnel with HIV transmission associated with occupational exposure, and another 138 reports of possible transmission to date.[2] For health care personnel exposed through percutaneous means to HIV-infected blood, the estimated risk for HIV infection is 0.3%.[2] Risks associated with a mucous membrane exposure are estimated to be 0.09%.[2] Risks for HIV seroconversion after a percutaneous exposure have been found higher for those exposed to a larger quantity of blood, (i.e., a device visibly contaminated with blood, a needle being placed directly in a vein or artery, or a deep injury) or when the source patient was terminally ill with AIDS.[2]

Transmission of HBV poses a risk to health care workers. In 1994, approximately 1,000 health care workers were infected with HBV from occupational exposure.[2] Since implementation of routine preexposure vaccination of health care personnel and precautions to prevent exposure to blood, there has been a significant decrease in HBV infection among health care personnel.[2] HBV is transmitted by mucosal or percutaneous exposure to blood and serum-derived body fluids from persons with acute or chronic infection. The risk of developing clinical hepatitis from exposure to the blood that was both hepatitis B surface antigen (HbsAg) and hepatitis E antigen (HbeAg) positive was 22 to 31%.[2] Any person who is seropositive for hepatitis B surface antigen can be infectious. The CDC recommends that health care personnel who have routine contact with blood and bodily fluids be vaccinated.[3] For applicable settings, the OSHA standard requires that hepatitis B vaccine be made available to personnel with occupational exposure to blood, at the employer's expense.[4]

American Academy of Ophthalmology®
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HCV is the cause of most parenterally transmitted cases of non-A, non-B hepatitis in the U.S. There is no vaccine currently available and postexposure prophylaxis has not appeared effective in preventing infection. HCV is thought to be transmitted relatively rarely through occupational exposure to blood.[2] The incidence of seroconversion after percutaneous exposure to an HCV-positive source is estimated to be 1.8%.[2] Hepatitis C virus (HCV) has been isolated in tears and aqueous humor.

Adenovirus has been the main cause of nosocomial outbreaks of conjunctivitis. These outbreaks have mostly occurred in eye clinics or offices. Adenovirus can survive for long periods on environmental surfaces and ophthalmic instruments can become contaminated and transmit infection. Handwashing, glove use and disinfection of instruments can all help to prevent or limit the transmission of adenovirus. Infected personnel should not provide patient care for the duration of symptoms after onset of adenoviral conjunctivitis

Background

The National Society to Prevent Blindness, in cooperation with the American Academy of Ophthalmology assembled a Task Force to examine the risk of acquiring HIV infection in the course of eye examinations and treatments. The Task Force helped develop precautions to reduce spread of pathogens that might be present in tears.[5]

In August 1987, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for the prevention of HIV transmission in a health-care setting.[6] This was followed two months later by a joint advisory notice from the U.S. Department of Labor and the U.S. Department of Health and Human Services regarding the protection against occupational exposure to HBV and HIV.[7] These documents addressed the risk that health care workers may face in the course of their duties and made broad recommendations labelled universal precautions that all health care workers should follow. Neither document distinguished the risks and needs of healthcare workers in ophthalmology from any other health care occupation.

In June 1988, the CDC further clarified their recommendations, particularly as they relate to the protection of health care workers, by stressing the far greater risk of bloodborne viral infections (e.g., HIV and HBV) posed by blood and blood-contaminated bodily fluids than by such bodily secretions as tears.[8] In that document, they noted that "Universal precautions do not apply to ... nasal secretions, sputum, sweat, tears... unless they contain visible blood." Thus, normal tear exposure does not require bloodborne pathogen precautions. In June, 2001, the U.S. Public Health Services updated recommendations for the management of occupational exposures to HBV, HCV and HIV.[3]

In March 1992, the Occupational Safety and Health Administration (OSHA), issued a set of regulations entitled, "Occupational Exposure to Bloodborne Pathogens, "which requires that employers establish safeguards which protect workers against hazards related to bloodborne pathogens.[4] These regulations require identification of who is at risk of occupational exposure, the communication of hazards to employees at risk for exposure, exposure prevention control measures, and what to do if an exposure occurs. In April 2001, the Needlestick Safety and Prevention Act became effective, revising the bloodborne pathogens standard to require employers identify and make use of safer medical devices which can be used to reduce worker exposure.[9]

In 1992, the American Academy of Ophthalmology Public Health Committee developed updated recommendations for ophthalmic practice in relation to HIV.[10] The Committee noted that there were two distinct areas of concern to ophthalmic medical personnel and patients:

1. Transmission of ocular surface infectious agents such as adenovirus or herpes virus. Prevention of transmission of these pathogens requires good hygienic techniques, such as routine hand washing, tonometry cleaning and trial contact lens disinfection.

2. Transmission of bloodborne pathogens such as HIV or HBV. Prevention of transmission of these agents requires the use of bloodborne pathogen precautions, which include the proper use of gloves, needle disposal and other precautions such as administering hepatitis B vaccine in workers exposed to bloodborne pathogens.

Recommendations

The Committee recommended specific measures that would provide adequate protection for the patient, for health care workers in the ophthalmic care setting, and for the ophthalmologist. This document updates four areas:

- Procedures for protection of the patient
- Procedures for protection of the staff
- Procedures for protection of the ophthalmologist
- Responsibilities toward patients with known or suspected HIV infection

I. Procedures for Protection of the Patient

Protection of patients from exposure to the HIV during examination and treatment of eye disorders incorporates

the application of good public health principles and specialized precautions. Since the infection was first recognized in 1981, there has been no evidence to indicate that the HIV has been transmitted through any of the diagnostic or surgical procedures performed by ophthalmologists. According to the CDC, the likelihood of transmission through contact with tears is extremely remote.[8] However, because the virus is potentially lethal, is present in surface epithelia in the eye and in low titers in tears and ocular fluids of infected individuals, and can (in theory at least) be transmitted through mucous membranes, public health officials have recommended that reasonable precautions be taken. Furthermore, because many HIV carriers may be unaware of their infection and show no sign of the disease, the following recommendations should be routinely used for **all** patients. Recommendations for the safe usage of ophthalmic instruments and contact lenses are provided. These guidelines represent good, general ophthalmic technique, because they reduce the risk of transmitting both bloodborne pathogens (HIV, HBV and HCV) and surface infectious agents (e.g., herpes simplex virus, adenovirus, etc.) likely to be encountered in patients presenting for eye examinations.

Recommendations

A. Handwashing.

Handwashing represents the single most effective means of avoiding the risk of transmitting or acquiring infections in the course of examination.[11] The CDC recommends that ophthalmic medical personnel performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients.[5] Handwashing should be encouraged when there is any doubt about the necessity for doing so. For routine handwashing, a vigorous rubbing together of all surfaces of the lathered hands is recommended for at least 10 seconds, followed by a thorough rinsing under a stream of water.[11] Plain soap can be used for handwashing for most routine activities. Gloves may be used as an extra margin of safety. When gloves are worn, handwashing is still recommended because gloves can become perforated and bacteria can grow rapidly on gloved hands. If there are cuts, scratches, or dermatological lesions (e.g., weeping lesions) on the hands, then use of gloves is advisable.

B. Eyedrops.

The bottle tip should not come into direct contact with the patient's tears or conjunctiva. If the tip does touch the patient, the bottle should be discarded.

C. Gowns, masks and protective eye wear.

Gowns, masks and protective eyewear are unnecessary for the usual ophthalmic examination.

D. Disinfection procedures.

Disinfection is a process to eliminate most or all pathogenic microorganisms from inanimate objects, such as medical devices or equipment.[12] This is usually performed using chemicals known as germicides or disinfectants. High-level disinfection kills all organisms and is performed suing a germicide which is regulated by the Food and Drug Administration. The CDC recommends that if there are questions about high-level disinfectants or how to disinfect a particular medical device, the office should contact the manufacturer of the product.[13]

The CDC has recommended the following, which are proven to inactivate infectious HIV, herpes simplex virus, and adenovirus.[5]

- Wiping clean and then disinfecting with bleach is recommended by the CDC as an effective way to inactivate HIV. Remove the entire prism from the tonometer and place it in a suitable receptacle that allows the applanating surface and adjacent 2–3 mm of the tonometer to be immersed in a 1:10 dilution of household bleach (sodium hypochlorite). One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution.[14] After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used while the other is being disinfected. Soaking the entire tip may eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach with a 5 to 10 minute exposure to a fresh solution of either 3% hydrogen peroxide, 70% ethanol, or 70% isopropanol can be followed. These solutions need to be changed at least twice daily.

Goldmann-type Tonometers

A recent study compared several methods of disinfecting Goldmann tonometer tips, which were inoculated with hepatitis C virus.[15] The methods that resulted in the greatest decrease in concentration of HCV RNA were a 5-minute soak in 3% hydrogen peroxide or 70% isopropyl

alcohol following by washing in cold water. A 5-second 70% isopropyl alcohol wipe was not as effective, and a 5-second wipe with povidone iodine was more effective than the isopropyl alcohol wipe in reducing HCV RNA.

The washes are important to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Schiotz Tonometer

The tonometer should be dissembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry) and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Non-contact Tonometers

The non-contact tonometer may not make contact with the cornea or tears, but may cause micro-aerosol formation. The front surface may be wiped with an alcohol-soaked sponge since it may occasionally touch the eye.

Digital Pneumotonometer

Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again. It is important to allow the alcohol to evaporate completely to avoid damage to the corneal epithelium.

Diagnostic Contact Lenses (Goldmann, etc.)

The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens are then vigorously wiped with an alcohol sponge
As an alternative, the inner cup may be filled to the rim or partly immersed within a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface of the lens as well as the contact portion without exposing the anti-reflective coating on the operator surface of the contact lens to the bleach. It is important to rinse to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Other Instruments That May Come Into Contact With Patients

The HIV is a fragile virus and there is no evidence of casual spread from surfaces of ophthalmic instruments. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and, thus, could conceivably be transmitted to other patients.[16] Therefore, if an instrument, such as a slit lamp biomicroscope, has been used for a patient who is suspected of having an ocular infectious disease, it is strongly recommended that the surfaces on the instrument be cleaned with alcohol or bleach.

Trial Fitting Contact Lenses

Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using a hydrogen peroxide or a chlorhexidene-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.[5]

E. Tissue Transplantation.

The Eye Bank Association of America has strict criteria in place to screen corneal and scleral tissue for transplantation, to prevent transmission of diseases. There have been no confirmed cases of occupational transmission of transmissible spongiform encephalopathies, such as Creutzfeld-Jakob disease. The CDC recommends use of stringent chemical and autoclave sterilization methods for heat-resistant instruments that come into contact with high infectivity tissues in patients with suspected or confirmed CJD.[17] For infection control of transmissible spongiform encephalopathies, the World Health Organization recommends the following in situations where there is contact with high infectivity tissues in patients with suspected or confirmed CJD:[18]

1. Use single-use surgical instruments
2. Avoid mixing instruments used on tissues of high infectivity vs. no infectivity
3. Destroy re-usable instruments, where possible
4. If destruction is not possible, decontaminate instruments.

The Risk of Acquiring HIV Infection from Ophthalmic Medical Personnel

The risk of patients being infected by an ophthalmologist or ophthalmic medical personnel who has been infected with the HIV is considered extremely remote. Standard office practices, as discussed above, will minimize even the unlikely risk of contamination of patients. Surgical patients are protected by the routine use of barriers (e.g., gloves). Certainly, an instrument that punctures the skin of an ophthalmologist or the surgical assistant must be removed from the operating field and sterilized. The surgeon or assistant must reglove after all bleeding has stopped and any residual blood has been removed.

The CDC Guideline for Infection Control in Healthcare Personnel also provides advice about management of patient contact and other situations when health care personnel have HIV and other illnesses which could be transmitted to patients.[19]

II. Procedures for Protection for the Staff

Protection of the ophthalmic medical personnel involves preventive measures to avoid infection with ocular surface contaminants (such as adenovirus or herpes simplex virus), as well as bloodborne pathogens (such as HIV, HBV and HCV).

Bloodborne pathogen precautions further reduce the unlikely risk of contamination of the ophthalmic medical personnel and patient, alike. Employers under OSHA's rule with health care workers who are exposed to bloodborne pathogens are required to establish a program that informs employees and employers of the risks of occupational exposure to bloodborne pathogens and how to reduce those risks.[3]

Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's bloodborne pathogen precautions; but exposure to human tears does require good office hygiene practices such as handwashing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.

As the prevalence of HIV infection continues to increase throughout the United States, it is inevitable that patients carrying HIV will be more commonly encountered in eye examining rooms and in surgery. Some of these patients will be known to be infected with the HIV, but in many, it will be unrecognized. All health care personnel engaged in delivering ophthalmic care to such patients might, in the course of their normal duties, be exposed to the blood of individuals who may be shedding the virus. Although the risk of infection in these circumstances appears to be extremely remote, precautions by health care employers and employees are justified as recommended by the OSHA and the CDC.

The following recommendations for hygienic procedures to be used in the delivery of eye care to patients are effective ways to minimize this risk as well as the risks of contracting or transmitting other much more common infectious diseases encountered in patients. Because it is impractical to identify all patients who may be carrying these infectious agents, these recommendations should be the routine for all patient encounters.

General Precautions Against Infection – Office

A. Handwashing.

The hands should be washed with soap and water and thoroughly dried on a fresh or disposable towel between each eye examination. Fingernails should be kept short and clean. The hands and fingers should be inspected frequently for cuts, abrasions, and breaks in the skin or paronychia.

B. Gloves.

The CDC suggests in its recommendations for the prevention of HIV transmission in health care setting, released in 1987[7], and updated in 1988[8], that:

> "All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with the blood or blood-contaminated fluids of any patient is anticipated. Gloves should be worn for touching blood and blood-contaminated fluids, for handling items or surfaces soiled with such fluids and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other bodily fluids. Hands should be washed immediately after gloves are removed.
>
> Health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
>
> Pregnant health care workers are not known to be a greater risk of contracting HIV infection than health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission."

In accordance with these recommendations, disposable gloves should be readily available for all ophthalmic medical personnel and they should be instructed regarding the rationale for wearing gloves and their appropriate usage. It should be noted particularly that gloves:

- Are not a substitute for handwashing, and
- Are for single use only, and should be discarded after each patient encounter.

C. Gowns and Masks.

Gowns and masks are unnecessary in the normal ophthalmic office setting.

D. Protective eye wear.

In situations when splashing with blood or blood-contaminated fluids may be anticipated, protective eyewear is indicated.

E. Handling of tissue.

In the course of assisting in the examination of eye patients, ophthalmic medical personnel may be required to handle the eyelids and surrounding facial skin and thus, may come in contact with tears and the conjunctival membrane. To minimize direct contact with these tissues, particularly if the patient has a known or suspected eye infection, ophthalmic medical personnel should be instructed in the use of gloves or in "no-touch" techniques involving the use of cotton-tipped applicators to stabilize the tissues whenever possible.

F. Hepatitis B vaccination.

Ophthalmic medical personnel who frequently come in contact with needles, blood or blood products are advised to receive hepatitis B vaccine to avoid infection with the virus.[3] OSHA regulations require that the employer make hepatitis B vaccine available to all employees who have occupational exposure.[4]

Procedures

A. Handling of sharp instruments.

The CDC has recommended that all health care workers adopt precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices[8]:

- During procedures
- When cleaning used instruments
- When disposing of used needles, and
- When handling sharp instruments after procedures

To prevent needlestick injuries, ophthalmic medical personnel should be instructed in the proper handling of needles, i.e., needles should not be recapped, or purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Health care workers should be instructed to place disposable syringes and needles, scalpel blades and other sharp items in puncture resistant containers following their use. Puncture resistant containers should be provided and should be located as close as practical to the area where needles and syringes are in use. Newer devices have engineering controls such as injury protections and needleless systems to minimize injuries.

OSHA's revised Occupational Exposure to Bloodborne Pathogens Standard now requires that the employers governed by this rule review annually and update to reflect changes in technology that could reduce exposure to bloodborne pathogens, and maintain a sharps injury log.[20] OSHA's Bloodborne Pathogens Standards applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials. However, workplaces with 10 or fewer employers are exempt from OSHA recordkeeping requirements, including a Sharps Injury Log.[21]

B. Fluorescein and Indocyanine green (ICG) angiography.

It is recommended that photographers and other health care workers who may come in contact with blood while performing fluorescein and ICG angiography wear gloves and adhere to the procedures as outlined in this section.

C. Contact lens fitting.

Ophthalmic medical personnel involved in the fitting of contact lenses should be instructed in the precautions outlined by the CDC for disinfection of lenses.[4]

D. Minor office surgical and diagnostic procedures.

During the performance of minor surgical and diagnostic procedures, particularly where contact with blood or blood-contaminated fluids may occur, gowns, disposable gloves and masks, and protective eyewear should be worn.

Surgery

Ophthalmic medical personnel assisting at eye surgery should be instructed to avoid the direct handling of needles and those parts of instruments that have come into contact with body tissues and fluids. Thus, needles should be manipulated with forceps or needle holders rather than by the gloved fingers, instruments should be held by the handle rather than by the tips, and the cleaning of instruments should be performed in such a way that accidental perforation of the gloves is avoided. If an instrument punctures a glove or the skin, it must be removed from the operating field and sterilized. These practices should be incorporated into standard operating room infection control procedures and should be monitored for compliance, as are other infection control procedures.

If an ophthalmic medical personnel does accidentally sustain a skin puncture, the following actions should be taken. The individual should temporarily discontinue participation in surgery (if possible) and cleanse the wound for five minutes with an antiseptic solution.

The wound should then be dressed with a bandage after rescrubbing. If there is no oozing or weeping of the wound, the person may reglove, and complete the surgery.

Under experimental conditions, it has been reported that oral polio vaccine virus was cultured from the laser plume after excimer laser ablation.[22] Another experimental study postulated that infectious virus particles could be aerosolized during excimer laser photoablation.[23] Another study using a model system did not find any transmission of virus by the excimer laser plume.[24] It seems prudcnt then to maintain the same procedures in excimer laser surgery procedures as practiced as in other surgical procedures, e.g., masks, gloves, sterilization of instruments, etc.

Management of Exposures

These recommendations are based on the U.S. Public Health Service Guidelines, published in 2001.[2] Occupational exposures are considered urgent medical concerns so that timely management can be administered.[2] Studies show that postexposure prophylaxis should be initiated as soon as possible, because it is most effective within 24 to 36 hours after exposure. However, even after 24 to 36 hours, it can be considered, because it might still be effective.

If a person has been exposed to a source person already known to be seropositive for HIV or there is a strong likelihood that the source person is HIV infected, then postexposure prophylaxis (PEP) can be initiated as soon as possible, in consultation with physicians with expertise in antiretroviral therapy and HIV transmission. If the source person's HIV status is not known, the use of PEP can be decided on a case-by-case basis. All persons with occupational exposure to HIV should receive follow-up counseling, testing and medical evaluation. For HIV PEP, recommendations include a basic 4-week regimen of drugs, if tolerated, and an expanded regimen for exposures that pose an increased risk for transmission.[2,25]

If the source person is seronegative for HIV, then baseline testing or further follow-up of the exposed health care personnel is not necessary. Otherwise, health care personnel should be tested for HIV within hours of exposure. Serologic testing should be made available to all health care personnel who are concerned that they might have been infected.

For personnel exposed to HBV, it is recommended to initiate the hepatitis B vaccine series to an unvaccinated person, and provide PEP with hepatitis B immune globulin or hepatitis B vaccine in appropriate cases, preferably within 24 hours.[1]

For personnel exposed to HCV, the Public Health Service does not recommend immune globulin or antiviral agents as PEP.[2] However, there have been studies outside the United States that have utilized interferon early in the course of acute hepatitis C to prevent the establishment of chronic hepatitis C.[2,26] In case of percutaneous or mucosal exposure to blood, the CDC recommends that health care institutions have policies to follow-up for HCV infection, which could include testing of the source person for anti-HCV antibodies, and follow-up testing for anti-HCV antibodies of the affected personnel, if the source person is found positive for HCV.[2]

If there is exposure to blood, fluid containing visible blood, or other potentially infectious fluid (not including tears), then the status of the source person should be evaluated for HIV, HBV, and HCV infection as soon as possible.

It is recommended that health care organizations have systems in place for prompt reporting, evaluation, counseling, treatment and follow-up of occupational exposures to bloodborne pathogens.[2] Health care personnel should be educated to report occupational exposures immediately after they occur, because treatment can be most effective if administered as soon as possible after the exposure. Employers subject to OSHA regulations are required to establish exposure control plans that include post-exposure follow-up and to comply with incident reporting requirements.[4]

III. Procedures for protection of the ophthalmologist

Ophthalmologists might be at risk of acquiring HIV, HBV or HCV infection in their professional activities from two major sources: 1) the patient examination, and 2) the setting of surgical intervention.

General Precautions Against Infection – Office

The ophthalmologist personally should follow the same procedures designed to protect office staff and described in Section II. These include handwashing, wearing of gloves where appropriate and taking precautions to prevent injuries caused by needles, scalpels and other sharp instruments. Avoid touching one's own eyelids or contact lenses with the fingers without thorough hand washing.

In the normal ophthalmic office setting, gowns, masks and protective eyewear are usually unnecessary except in situations when splashing with blood or blood-contaminated fluids may be anticipated.

Minor Office Surgical and Diagnostic Procedures

The universal precautions should be observed when performing minor procedures and intravenous fluorescein angiography. In addition to gloves and masks, protective

eyewear should be used if there is a possibility of blood or body fluid splashing.

Surgery

Ophthalmologists are probably most at risk of exposure to HIV and other bloodborne pathogens while performing or assisting in surgery. The following procedures are recommended during surgical procedures:

- Adopt universal precautions for all patients
- Wear gloves when performing all injections
- Handle suture needles with needle holders only
- Develop techniques for safe handling and transfer of sharp instruments
- Follow guidelines given in Section II regarding surgery

IV. Responsibilities Towards Patients with Known or Suspected HIV Infection

Like all physicians, ophthalmologists have a moral and ethical responsibility for providing care to all patients, regardless of whether they are known to be infected with HIV, are known to be seropositive or fall within a "high-risk" group.

Ophthalmologists and ophthalmic medical personnel are at little risk of contracting HIV infection in the course of routine clinical practice. Risks may be further minimized when dealing with those known to be seropositive or suffering from clinical AIDS, but one should remain cognizant of the fact that many seropositive individuals have not been tested. Given the above scenario, bloodborne precautions are warranted for all appropriate patients.

Conclusion

The risk of contracting HIV infection in the ophthalmic healthcare setting is estimated to be extremely remote. Although HIV has been isolated from tears and other ocular fluids, the titer is extremely low and is considered by many authorities to be below an inoculating dose. To date, there is no evidence that the infection has been acquired from contact with tears. However, it must be remembered that these precautions will be effective against other more infectious agents than may be encountered in patients with HIV infection. These OSHA and CDC guidelines are intended to help protect the public and ophthalmic medical personnel, and minimize transmission of bloodborne pathogens and surface infectious agents.

Additional Resources:

Further information on the CDC guidelines can be obtained by viewing the CDC website for Division of Healthcare Promotion http://www.cdc.gov/ncidod/hip/.

Further details on the OSHA regulations including regulations governing HIV and HBV research laboratories and production facilities can be obtained by viewing the OSHA website (http://www.osha.gov/) or ordering publications online (http://www.osha-slc.gov/OshDoc/Additional.html)

Occupational Safety and Health Bloodborne Infectious Disease
www.cdc.gov/niosh/bbppg.html

State needle safety legistation: www.cdc.gov/niosh/ndl-law.html

Exposure management resources:

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
1-888-448-4911

Needlestick! www.needlestick.mednet.ucla.edu

Hepatitis hotline 1-888-443-7232

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP
1-800-893-0485

HIV/AIDS treatment information service
www.hivatis.org

Date issued: March 1, 2002

Approved by: Quality of Care Secretariat

Acknowledgements:

The Academy gratefully acknowledges the valuable time, expertise and effort of the following individuals in reviewing this document: Gary Holland, M.D.; Elaine Chuang, M.D., Jay Pepose, M.D., Alice Matoba, M.D., Douglas Jabs, M.D., and Eric Donnenfeld, M.D., of the Ocular Microbiology and Immunology Group.

Fuse Replacement

Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further. (See Figure 44.)

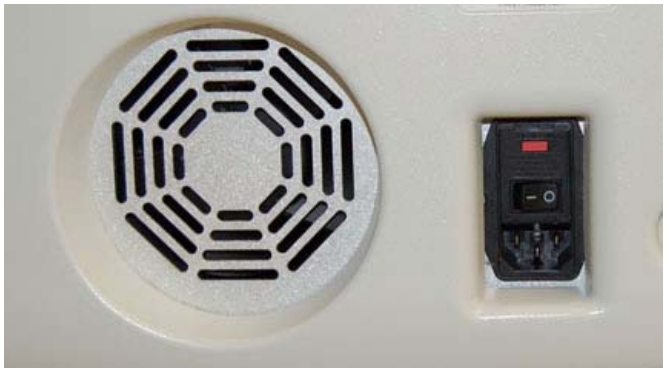

Figure 44 Power Entry Module

Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module. (See Figure 45.)

Figure 45 Opening the fuse holder cover

Remove the fuse holder. (See Figure 46.)

Figure 46 Removing the fuse holder

Remove the blown fuse or fuses from the fuse holder and replace it with a new fuse of same type and rating. (See Figure 47.) Re-insert the fuse holder.

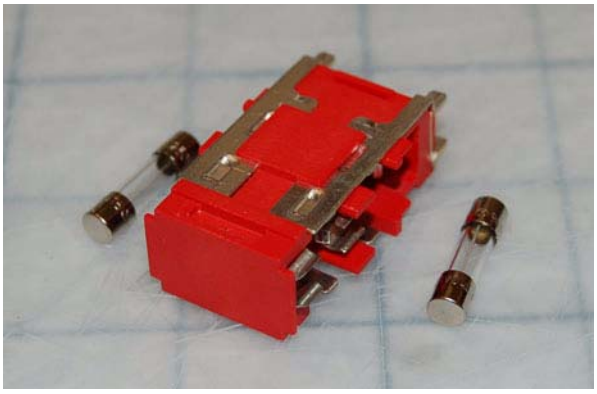

Figure 47 Fuses removed

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Replacement fuses are available from Clarity Customer Service.

.

Figure 48 Fuse holder re-inserted

Replace Illumination Lamp

WARNING: Appropriately power down and unplug the unit and allow the illumination lamp to cool before replacing it.

Replacement illumination lamps are available from Clarity.

Follow these steps to replace the illumination lamp:

1. If it is not already turned OFF, turn OFF the instrument according to the instructions found under Turning the System OFF (Stand-by Ready) on page 21.
2. Disconnect the main power cord from the wall.
3. Unplug the fiber optic cable from the front panel.

4. Remove the two screws from the lamp assembly drawer, the smaller panel with the black handle on the front.

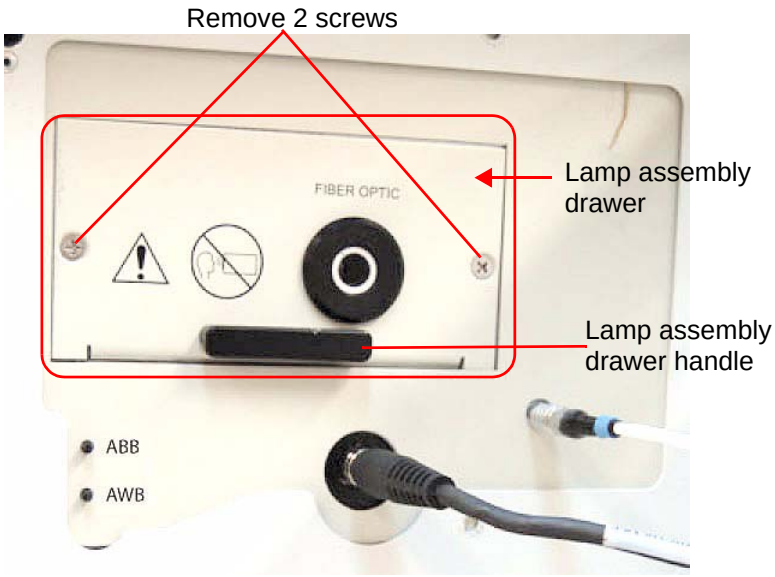

Figure 49 Front panel showing the lamp assembly drawer

5. Grip the handle on the lamp assembly drawer. Pull the drawer out slowly. Stop when the light bulb is fully exposed.
6. Just behind the socket and extending from the rear of the illumination lamp is a thick gray wire, the “lamp ejector” indicated in the picture below. Be prepared to grab or catch the illumination lamp unit as you gently rotate this wire toward you (rotate it up, or counterclockwise), which ejects the lamp. Remove the old illumination lamp.

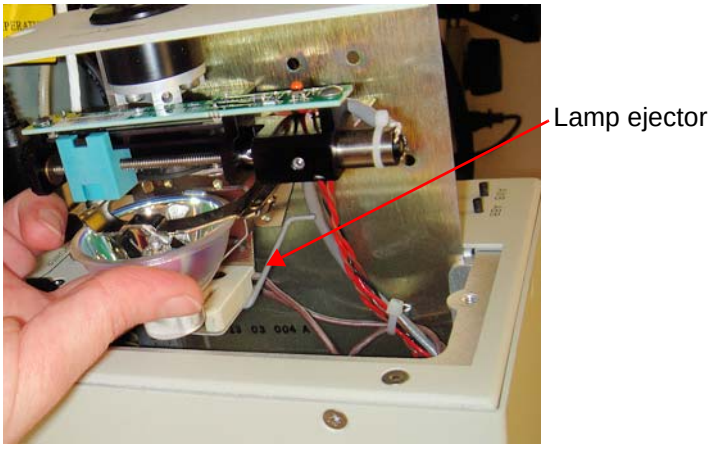

Figure 50 Removing the illumination lamp

CAUTION: Only touch the exterior surface of the illumination lamp. Do not touch the bulb, which is located in the center of the reflector, nor the inner (concave) surface of the reflector. Skin oils will adhere to the bulb and reflector, which reduces the cooling efficiency of the bulb and thereby creates a hot-spot leading to premature burnout. Handle by the outside of the lamp only, as shown.

7. **Holding the new lamp only on the outside,** as shown, replace it in the assembly, aligning the two pins in the rear with the corresponding tracks in the socket and pushing it gently and evenly into place.
8. Check the position of the new bulb to make sure that the reflector of the bulb is located in the center of the lamp socket's opening.
9. Push the lamp assembly drawer back in carefully. Use caution to avoid pinching wires in the area.
10. Replace the two screws on the small front panel.

Key Validation

Note: New RetCam3 systems ship with their license key already registered and validated. However, significant changes to the system hardware or a re-load of the system software for any reason (including software upgrade) may require you to perform the key validation process as described below. Key validation requires that you get a license key from Clarity to use the revamped system, and you cannot request this key until after installation is complete. Since it may take up to two (2) business days to obtain a license key after submitting a request, we recommend that you effect system or software upgrades when you can manage two business days without use of the system.

Note: To ensure the preservation of your patient data and images, we strongly recommend that you perform a complete backup of the system's images before you begin any software installation.

When key validation is necessary, the Key Validation dialog appears when you start the system (and each time thereafter until you complete this step), before the Site Awareness dialog.

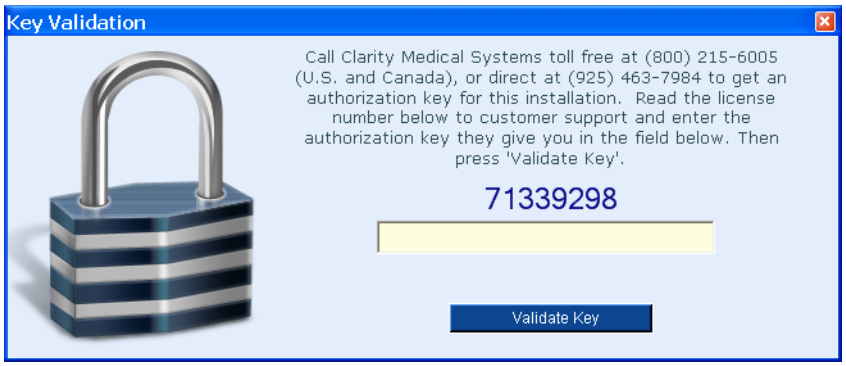
Key Validation
Call Clarity Medical Systems toll free at (800) 215-6005 (U.S. and Canada), or direct at (925) 463-7984 to get an authorization key for this installation. Read the license number below to customer support and enter the authorization key they give you in the field below. Then press 'Validate Key'.
71339298
Validate Key

Figure 51 Key Validation dialog

Follow the instructions on screen: Call Clarity and provide to the customer support representative the large license number in the dialog (71339298 in the example above), which is unique for your system. You will be provided in turn a unique authorization key.

Tip: You may also send the license number via email to **service@retcam.com** and receive the authorization key by return email.

You must enter the authorization key in the field and click **Validate Key** to access the system software. If you call, to make sure you enter the number correctly, we recommend you do not hang up until the number is accepted.

Technical Support

Technical Support Contact Information

Customers outside the US, please contact your distributor for technical support.

In the US, you have the following options:

Telephone

Toll-free: (800) 215-6005

Fax: (925) 251-0078

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

After hours: Please leave a message as the messages are checked during the evening hours.

Send correspondence to:

Clarity Medical Systems, Inc.

5775 West Las Positas Blvd.

Pleasanton, CA 94588

USA

Email

service@retcam.com

Our US technical support staff will respond to your questions as soon as a staff member is available. In most cases, you should receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur service charges. Please ask for an hourly quotation before incurring charges.

Service Information

Service information is available separately in the RetCam3 Service Manual.

RetCam3 components are typically return-to-factory components and can be repaired by only Clarity personnel and/or our qualified distributors. The Service Manual contains information on user-replaceable parts and/or instructions to remove components for return for factory repair.

8 User Preferences

The section describes the User Preferences available, including:

- System Identification/Institution
- Setting Pre-configuration Imaging defaults for New Exams
- Changing Date/Time
- Changing Speaker Volume
- Setting Printer defaults
- Setting Network connections

Select the cog icon in the lower right hand corner to access the User Preferences.

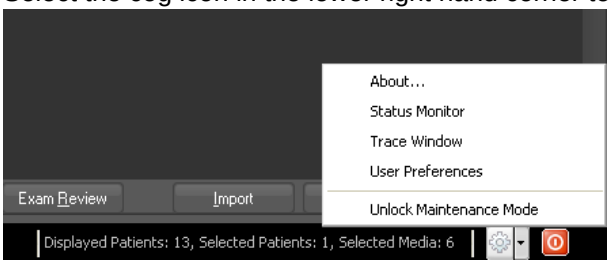

Figure 52 Access User Preferences

Click **About** to identify the RetCam software version. Click **OK** to exit.

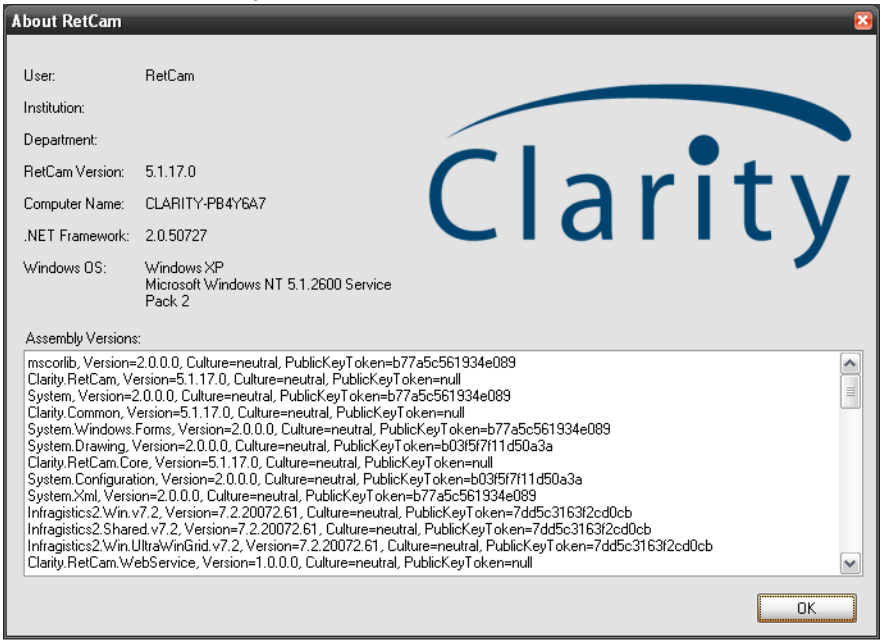

Figure 53 About Clarity software

Select **User Preferences**.

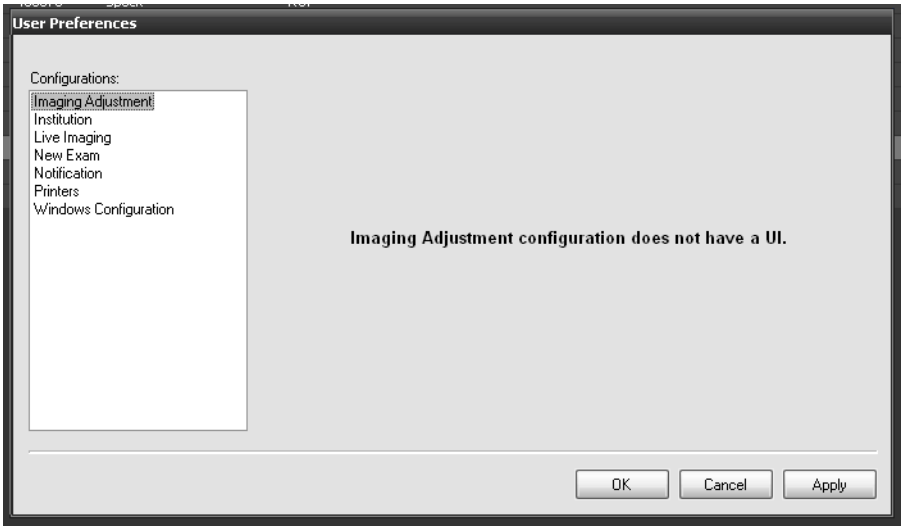

Figure 54 User Preferences screen

Select from the following options:

Imaging Adjustment	Not available
Institution	Add the name of the Institution, Department and Location.
Live Imaging	Not applicable
New Exam	Set the Pre-set Imaging Configurations for new exams.
Notification	Not applicable
Printers	Set the Default Image and Report Printer.
Windows Configuration	Set Date and Time, Display, Network Connections, Printers and Faxes, Region and Language, Security Center and Sound.

Institution

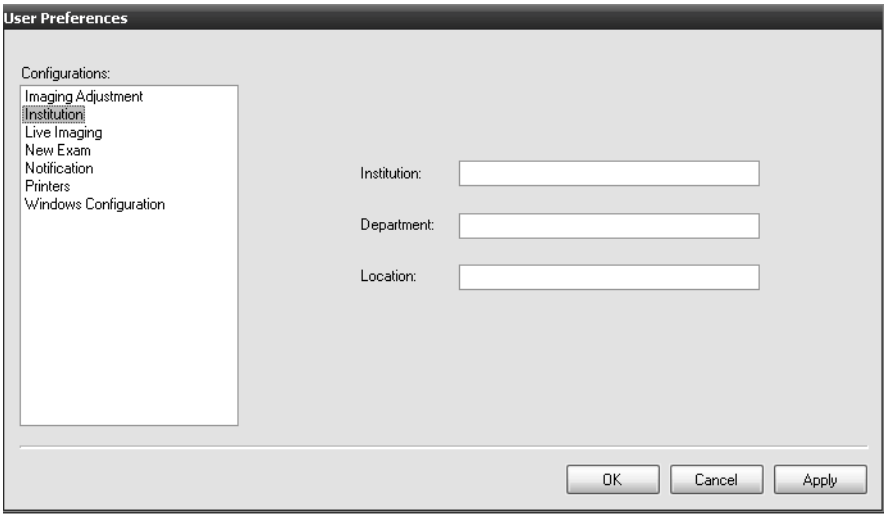

Figure 55 User Preferences: Institution

New Exam

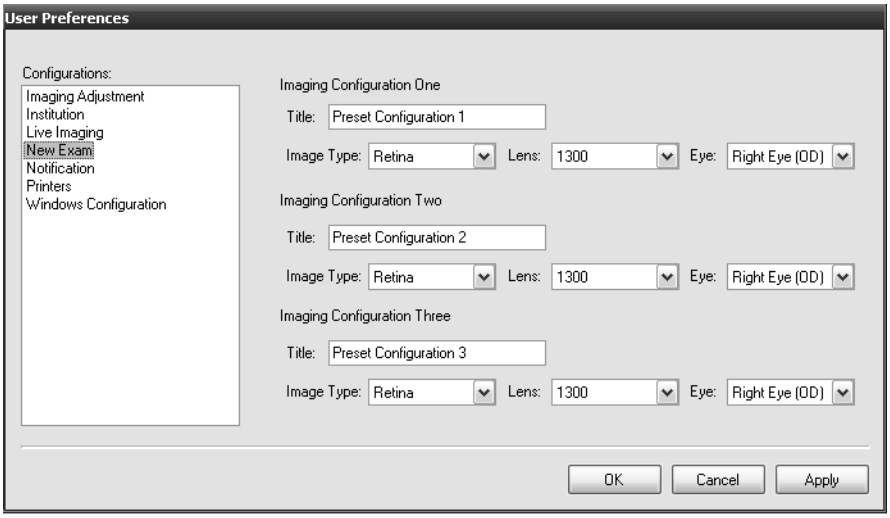

Figure 56 User Preferences: New Exam

Once the New Exam preset configurations are adjusted, click **Apply** to initiate the change or **Cancel**. Click **OK** to exit the screen.

Printers

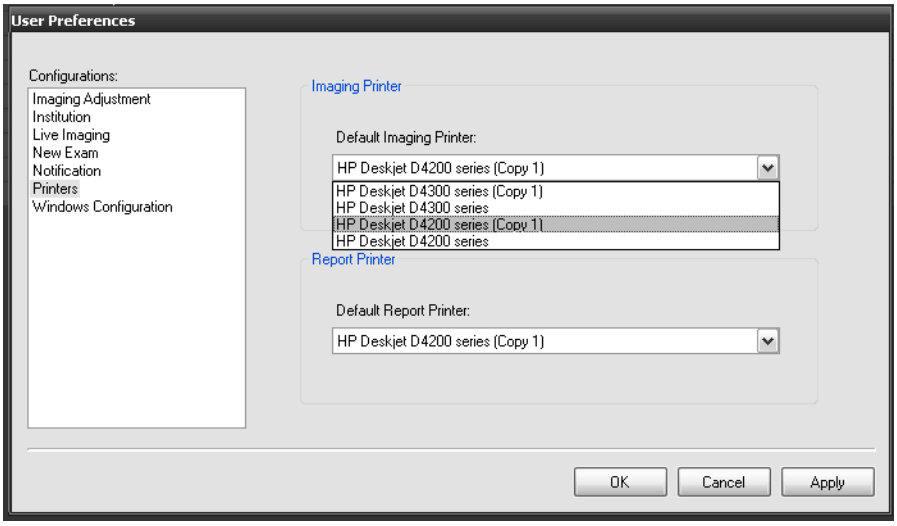

Figure 57 User Preferences: Printers

Select the default printers, then click **Apply** to initiate the change or **Cancel**. Click **OK** to exit the screen.

Windows Configuration

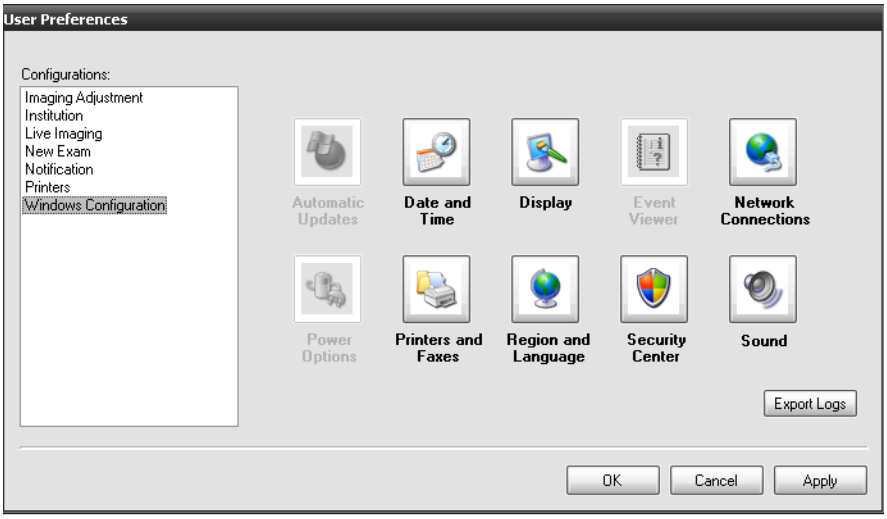

Figure 58 User Preferences: Windows Configuration

Select the desired Windows configuration icon and make changes where needed. Click **Apply** to initiate changes or **Cancel**. Click **OK** to exit the screen.

9 Technical Specifications

Hardware

Physical

- 26”(660 mm) wide x 24”(610 mm) deep x 54”(1372 mm) minimum height
- Approximately 200 lbs. (91 Kg) fully loaded

Electrical

- Ratings: 100-240 V~, 50/60 Hz, 700 VA
- Fuses: 3AG 10A 250V slo-blo 5 x 20 mm
- Power consumption: 700W with all options
- Detachable hospital grade power cord

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures and humidity, upright, on a level surface, with the brakes applied to the front casters.

Condition	Operating	Storage and Transport
Temperature	50º to 95º F (10º to 35º C)	-20º to 122º F (-29º to 50º C)
Relative Humidity	30% to 90% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Note: Specifications subject to change without notice.

10 License Agreements

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This Software and accompanying written materials are provided with Restricted Rights. Use, duplication, or disclosure by the U.S. Government is subject to restrictions applicable to commercial computer software (under FAR 52.227--19 and DFARS 25.227-7013). Contractor/manufacturer is Clarity Medical Systems, Inc., 5775 West Las Positas Boulevard, Pleasanton, CA 94588.

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Any attempt to decompile, reverse engineer or otherwise copy this software shall be considered a breach of this agreement.

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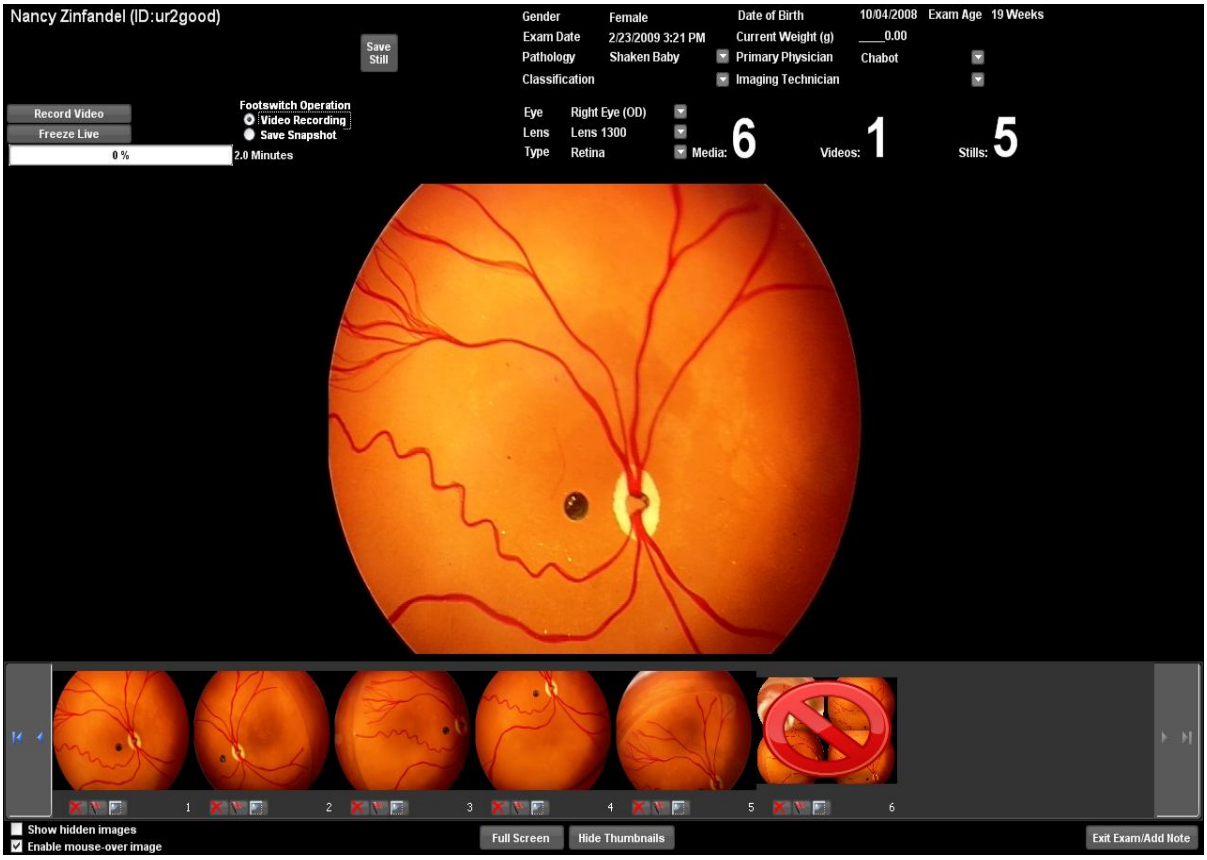
User Manual Addendum
RetCam Physician Information for Screening of Retinopathy of Prematurity



CE

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

Clarity medical systems

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EC REP

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RETCAM PHYSICIAN INFORMATION-
SCREENING FOR RETINOPATHY OF PREMATURITY

WARNING

The information in this section is provided by Clarity Medical Systems, Inc. solely as an information service to physicians for the screening of Retinopathy of Prematurity (ROP). It is not intended to offer medical advice and does not preclude the necessary assessments, judgments and medical determinations that are the exclusive responsibility of the physician. The information in this section is essential to the screening of ROP with the RetCam Ophthalmic Imaging System and presumes that the reader has read the rest of this User Manual and thoroughly understands it.

INDICATIONS FOR USE

- General ophthalmic imaging including retinal, corneal, and external imaging;
- Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP);
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease) or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants.

*References:

1. Cryotherapy for Retinopathy of Prematurity Cooperative Group. Multicenter trial of cryotherapy for retinopathy of prematurity: preliminary results. Archives of Ophthalmology 1988; 106(4):471-479.
2. Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.

CONTRAINDICATIONS

Any patient with a perforating injury to the globe should not be imaged with the RetCam until the wound is repaired.

In the case of an eye infection, and if at all possible, use of the RetCam should be delayed until treatment for the infection has been rendered.

The RetCam should not be used to image a patient determined to be unstable by a neonatologist.

WARNINGS

Warning: Carefully inspect and clean the lens piece before each use. DO NOT use if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye. See Section 7 of this User Manual for proper cleaning instructions.

Warning: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of exposure time necessary; no greater than 5 minutes per eye.

Warning: Use care when imaging the eye; i.e., the lens tip is immersed in coupling gel, and does not contact the eye directly. Ensure the camera is supported (held) in a manner that does not put direct pressure on the cornea. Practice with the simulator eye model is recommended prior to patient imaging.

Warning: A risk/benefit ratio must be assessed before confirming a patient for RetCam imaging if they are photosensitive, concomitantly exposed to photosensitizing agents, or aphakic.

Warning: To mitigate the potential for excess light exposure of the user, the operator should avoid looking directly at the illuminated light source

PREPARATION

Warning

Precaution: Clarity Medical Systems, Inc. strongly recommends that the user complete the hands-on training program offered by Clarity Medical Systems, Inc. and study all of the online training modules found on the Clarity Medical Systems, Inc. website at www.claritymsi.com before imaging a patient.

- To minimize stress for the neonatal patient, schedule the RetCam imaging at a time when the baby is relatively calm and other evaluations are not scheduled immediately preceding or following use of the RetCam.
- Institute patient comfort and movement restricting measures for neonates and infants such as swaddling, pacifiers, reduced room lighting, and reduced noise.
- Wash your hands and wear gloves to prevent cross contamination.
- Instill topical anesthesia drops into the patient's eyes.
- For retinal imaging, dilate the pupils to at least 6mm.
- Hold the infant's head gently, but securely, in a face-up position.

Warning

When using a lid speculum on neonates, make sure that the lid speculum is appropriately sized for the neonate in order to reduce stress from discomfort.

USING THE RETCAM

Warning

Retinal Fields

Instill topical anesthetic. Instill ophthalmic coupling gel into the first eye to be imaged or alternatively a bolus of gel may be applied to the camera lens tip.

Use a lid speculum to retract the lids and allow for placement of the lens to be centered over the pupil.

Precaution: Only gentle physical contact between the coupling gel and the lens is necessary. Avoid pressure directly against the eye as excessive pressure may cause visible pulsations of the central retinal artery and branches. Resulting vascular changes may interfere with assessment of retinal vascularization.

To maximize photo-documentation of the retina, it is suggested that the following five (5) views be captured:

1. Posterior pole
2. Temporal retinal field
3. Nasal retinal field
4. Superior retinal field
5. Inferior retinal field

The imaging procedure as outlined above will typically provide adequate retinal coverage to assess Zones 1 and 2. It is not uncommon to miss some of Zone 3 in the temporal image, but since disease isolated to Zone 3 does not result in ROP treatment, the clinical impact is negated. **However, before discharge from an ROP screening program, it is important to fully assess the entire retina, including Zone 3.**

SCREENING FOR RETINOPATHY OF PREMATURITY (ROP)

Chiang, et. al. reported the results of a prospective trial to measure the accuracy, reliability, and image quality of RetCam wide-field digital images to screen for ROP.

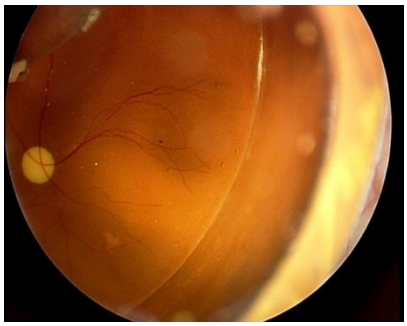
In the study, eyes from 67 consecutive infants underwent RetCam wide-field digital retinal imaging by trained neonatal nurses using a standard protocol of 3 images per eye and the 130 degree lens. The infants were 31 to 33 weeks and/or 35 to 37 weeks postmenstrual age (PMA).

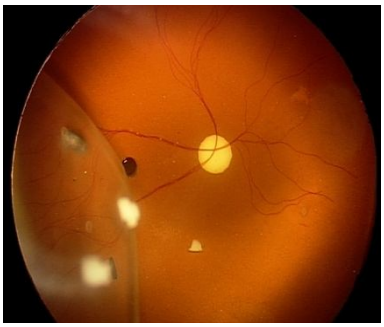
The protocol for this study required that a minimum of 3 images (posterior, temporal, and nasal photographs) be consistently captured for each of the patients. “Each image set

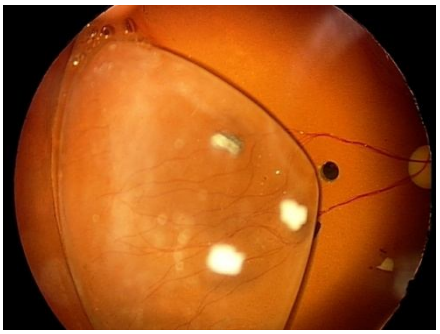
included up to 2 additional images from any area of the eye, if felt by the nurse to contribute diagnostic information."

The below images were taken using a RetCam 130 Degree lens on a plastic “practice" eye that has a simulated retinal detachment. The “vascular” information is not meant to accurately represent the arcades, but provide objects to focus on. The glare seen on the images is due to reflections from the plastic eye and is not indicative of human corneal reflections.

Chiang’s three position imaging technique is illustrated below with the three separate 130 degree images, nasal, posterior pole, and temporal. These images show that there is overlap (yellow dot representing the optic nerve in each view) of the digital images.

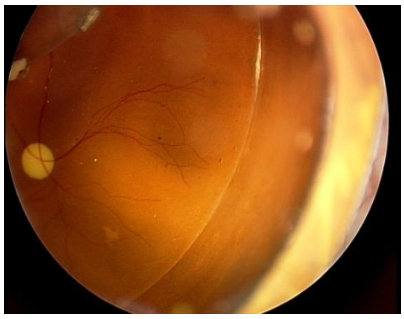

OS Nasal View


OS Posterior Pole View

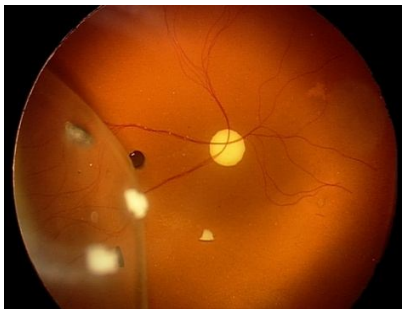

OS Temporal View

The below set of images represents the method taught by Clarity of taking five images; Chiang's approach plus two more images, superior and inferior. As can be seen, there is overlap in all images.

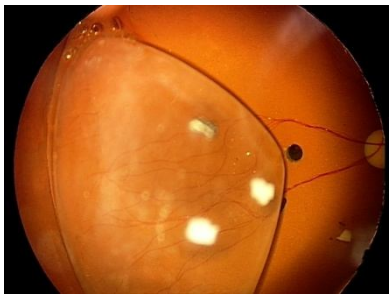
OS Superior View



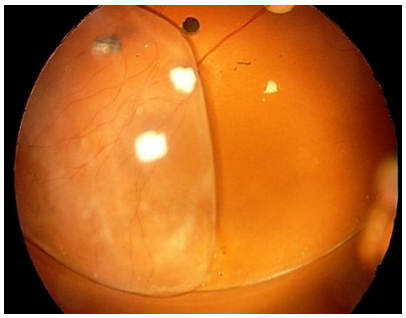
OS Nasal View



OS Posterior Pole View



OS Temporal View



OS Inferior View

Images were interpreted by three expert retinal specialist graders who provided a diagnosis (No ROP, Mild ROP, Type 2 Pre-Threshold ROP, treatment requiring ROP, or unknown) and an evaluation of image quality. The diagnosis definitions of Type 2 Pre-Threshold ROP and treatment requiring ROP are found below. Mild ROP was defined as ROP less than Type 2 disease. A diagnosis of unknown meant the grader was uncomfortable making a diagnosis from the data provided. Findings were compared with a reference standard of binocular indirect ophthalmoscopy (BIO) by experienced pediatric ophthalmologists. The target condition (referral warranted disease-the presence of Type 2 pre-threshold or worse ROP) in this study that supports the use of RetCam as an ROP screening tool is Type 2 Pre-threshold ROP (Zone 1, Stage 1 or 2, without plus disease, or Zone 2, Stage 3, without plus disease) or treatment requiring ROP (Zone 1,

any stage, with Plus disease; Zone 1, stage 3 without plus disease; or Zone 2, stage 2 or 3 with Plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) at 35-37 weeks PMA. The reported study results are presented below.

PERFORMANCE DATA

The tables below depict the study outcomes. Tables 1A, 1B, and 1C contain the individualized data from each of the three independent Graders A, B, and C respectively. Table 2 identifies the sensitivity and specificity for the population studied in the referenced article.

Table 1: Cross-Classification of Graders

Table 1A: 35-37 Weeks. Cross-classification from Grader A versus BIO

		Reference Standard: BIO	
		Type 2 pre-threshold ROP or treatment-requiring ROP	No ROP or Mild ROP
Grader A	Type 2 pre-threshold ROP or treatment-requiring ROP	26	5
	Unknown	0	6
	No ROP or Mild ROP	0	83
	Total	26	94

Based on a review of the RetCam images, Grader A concluded that 31 sets of images had Type 2 pre-threshold ROP or treatment-requiring ROP including all 26 cases determined by BIO to be Type 2 pre-threshold ROP or treatment-requiring ROP. Grader A was unable to make a determination for 6 sets of images. 83 sets of images were concluded by Grader A to have no ROP or mild ROP.

Table 1B: 35-37 Weeks. Cross-classification from Grader B versus BIO

		Reference Standard: BIO	
		Type 2 pre-threshold ROP or treatment-requiring ROP	No ROP or Mild ROP
Grader B	Type 2 pre-threshold ROP or treatment-requiring ROP	26	6
	Unknown	0	8
	No ROP or Mild ROP	0	80
	Total	26	94

Based on a review of the RetCam images, Grader B concluded that 32 sets of images had Type 2 pre-threshold ROP or treatment-requiring ROP including all 26 cases determined by BIO to be Type 2 pre-threshold ROP or treatment-requiring ROP. Grader B was unable to make a determination for 8 sets of images. 80 sets of images were concluded by Grader B to have no ROP or mild ROP.

Table 1C: 35-37 Weeks. Cross-classification from Grader C versus BIO

		Reference Standard: BIO	
		Type 2 pre-threshold ROP or treatment-requiring ROP	No ROP or Mild ROP
Grader C	Type 2 pre-threshold ROP or Treatment-requiring ROP	26	14
	Unknown	0	0
	No ROP Or Mild ROP	0	80
	Total	26	94

Based on a review of the RetCam images, Grader C concluded that 40 sets of images had Type 2 pre-threshold ROP or treatment-requiring ROP including all 26 cases determined by BIO to be Type 2 pre-threshold ROP or treatment-requiring ROP. Grader C was able to make a determination for all of the sets of images. 80 sets of images were concluded by Grader C to have no ROP or mild ROP.

Table 2: **Statistics and 2x2 Cross-Tabulation Components by Grader**

	Performance For Type 2 Threshold ROP Or Worse			
Grader	sensitivity	~95% CI for sens.	specificity	~95% CI for spec.
A	1.0 (26/26)	(0.868, 1.0)	0.883 (83/94)*	(0.802, 0.933)
B	1.0 (26/26)	(0.868, 1.0)	0.851 (80/94)**	(0.765, 0.909)
C	1.0 (26/26)	(0.868, 1.0)	0.851 (80/94)	(0.765, 0.909)

* This counts as false positives the 6 sets of images classified as unknown by Grader A and 'mild ROP or less' by the reference standard.
** This counts as false positives the 8 sets of images classified as unknown by Grader B and 'mild ROP or less' by the reference standard.

Unknowns in this study were treated as false positives (referral-warranted disease) for statistical purposes in Table 2 because in the clinical setting such a result would result in examination by BIO. None of the BIO referrals were missed by the RetCam Graders resulting in 100% sensitivity results for each Grader. Due to "over referral" by two of the Graders and the inclusion of unknowns as referrals, specificity results for the graders ranged from 85% to 88%.

IMAGE QUALITY

Before providing a diagnosis for each image set, the 3 retinal specialist graders assessed the technical quality of the images for "adequate", "possibly adequate" or "inadequate". Each of them found that images taken at 35-37 weeks PMA by trained NICU nurses were technically "adequate" or "possibly adequate" at a rate of 93.3% to 100%.

REFERENCE

Chiang MF, Wang L, Busuioc M, et al (2007). Telemedical Retinopathy of Prematurity Diagnosis; Accuracy, Reliability, And Image Quality. *Arch Ophthalmology*, **125** (11), 1531-1538.

TRAINING

Clarity Medical Systems, Inc. advocates training in the use of the RetCam System as a requirement for all personnel who will either acquire images using the RetCam or review images taken by the RetCam. This includes physicians, nurses, ophthalmic photographers and ophthalmic technicians working in the environment where the patient receives care.

For instance, in the Chiang study, trained neonatal nurses performed all of the imaging evaluations in the Neonatal Intensive Care Unit (NICU). Training is accomplished in several ways.

- At the time of installation of a new RetCam System, a Clarity Medical Systems, Inc. representative is present to provide a didactic tutorial, a demonstration of the product and supervised, hands-on experience in the use of the System. The comprehensive training session is conducted by Technical Support representatives from Clarity Medical Systems, Inc. and/or Clarity Medical Systems, Inc.'s Clinical Services Manager. Follow-up online software training support is also made available.

- An integral section of the training includes a required performance test for each of the attendees at the training session. The newly trained user takes the images using the Clarity practice head and eye first, moving on to a patient if available and appropriate. New users must demonstrate that they can successfully, capture the images as well as perform all data entry, processing, storage, review and export functions attendant to digital documentation systems.

- Comprehensive Training Modules are readily available for immediate access and review at www.claritymedicalsystems.com.

- If additional on-site training is requested at any time, Clarity Medical Systems, Inc. will provide the necessary support.

- Customer Service is available 24 hours a day, 365 days a year at telephone number 1-800-215-6005. Technical Representatives are available to respond to questions. If inquiries require additional clinical input, the Clinical Service Manager and/or the Chief Medical Officer may be consulted as needed.

The graders in the previously referenced Chiang study were ophthalmic specialists with extensive experience reviewing RetCam images and were responsible for ROP examination in a tertiary care medical center. ROP screening with the RetCam requires that image graders be ophthalmic specialists with the necessary medical experience to effectively evaluate RetCam images for the presence or absence of ROP disease.

PHOTO DOCUMENTATION

The RetCam System creates permanent, still or video, digital images of the retina, cornea and external structures of the eye. The original images cannot be altered. A digital image is not subject to the predictable inaccuracies associated with the current practice of viewing a structure and subsequently making hand written notes and/or paper sketches or drawings in an attempt to record what was seen.

Digital images are readily available for direct comparisons over time. As the images are captured at various intervals, they can be displayed side by side on a screen, allowing the physician to track the progress of disease and determine the need for any intervention. These permanent images can become a part of the patient's medical record.

ADVERSE EVENTS

The RetCam Imaging System has been used in over 60 countries. More than 700 devices have been distributed worldwide. It is estimated that over 1.5 million eye imaging examinations have been performed with the RetCam Imaging System. The RetCam Imaging System has an excellent record of safety. Table 3 identifies three clinical risks which could conceivably occur as well as recommended steps to mitigate each of them.

Table 3: RetCam Risks and Mitigation

RISK	MITIGATION
Cross Contamination	Infants in a NICU may be particularly vulnerable. Infection control in any acute care setting is of paramount concern. Standard techniques to reduce cross contamination include strict hand washing procedures and adherence to policies in keeping with the institution's standard practice. RetCam users should wear gloves. The RetCam lens must always be cleaned according to Clarity's instructions before and after each use.
Physiological Stress	NICU infants are particularly subject to the risk of physiological stress from any procedure. One highly effective way to avoid undue stress as a result of a RetCam evaluation is to assure that the user is qualified by education and experience to perform the evaluation. Training in the use of the RetCam System is mandatory. Those personnel who are the medical/nursing staff in a NICU setting are uniquely sensitive to the special needs of stress avoidance for their patients as well as monitoring stress experience by their patients. Preparation of the infant and the environment are strongly recommended. Careful ergonomic positioning of the RetCam relative to the patient and user is important to facilitate an efficient screening procedure. The selection of a lid speculum appropriate for the size of the infant and the gentle insertion of it minimizes stress prior to and during the examination. The combination of qualified, trained personnel and a well-planned procedure greatly reduces the risk of physiological stress. Training modules are available on line at www.claritymsi.com.
Ocular Pressure	Only gentle contact between the coupling gel and the lens is necessary to create an optical bridge that effectively couples the light. Physical contact with the cornea is not required and should be avoided. Undue pressure on the eye may interfere with visualization and may be uncomfortable for the infant increasing stress. The user must be qualified by education and experience to perform the imaging examination. Training in the use of the RetCam System is mandatory. Follow-up and advanced user training is also available. Training modules are available on line at www.claritymsi.com.

RetCamphysicianinformation.doc

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